

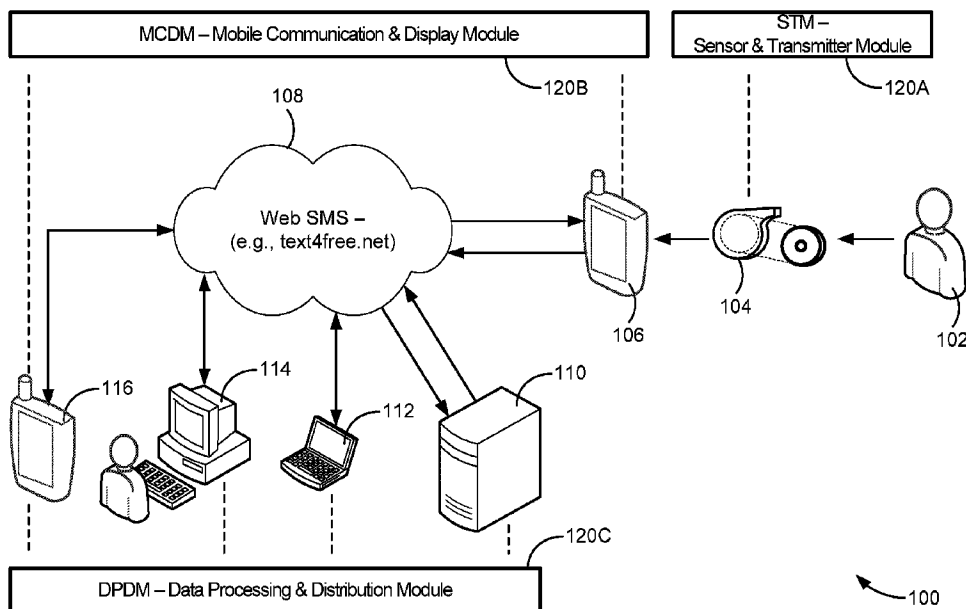


(86) Date de dépôt PCT/PCT Filing Date: 2014/03/13
(87) Date publication PCT/PCT Publication Date: 2014/10/02
(45) Date de délivrance/Issue Date: 2021/03/23
(85) Entrée phase nationale/National Entry: 2016/09/12
(86) N° demande PCT/PCT Application No.: US 2014/025693
(87) N° publication PCT/PCT Publication No.: 2014/160042
(30) Priorité/Priority: 2013/03/14 (US61/785,696)

(51) Cl.Int./Int.Cl. *G16H 50/20* (2018.01),
A61B 5/00 (2006.01), *A61B 5/087* (2006.01),
H04W 4/38 (2018.01)
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(54) Titre : SYSTEME DE SURVEILLANCE DE MALADIE BASE SUR INTERNET (IDMS)

(54) Title: INTERNET-BASED DISEASE MONITORING SYSTEM (IDMS)



(57) Abrégé/Abstract:

A medical device is provided to monitor the patient's respiratory condition. The device includes a flow chamber housing, a vane mounted to an interior surface of the flow chamber for pivoting bidirectional movement about an axis in a central portion of the flow chamber housing, and a sensor transmission module housing detachably coupled to the flow chamber housing. A system is also provided having a sensor transmission module housing configured for detachably coupling to the medical device.

ABSTRACT

A medical device is provided to monitor the patient's respiratory condition. The device includes a flow chamber housing, a vane mounted to an interior surface of the flow chamber for pivoting bidirectional movement about an axis in a central portion of the flow chamber housing, and a sensor transmission module housing detachably coupled to the flow chamber housing. A system is also provided having a sensor transmission module housing configured for detachably coupling to the medical device.

INTERNET-BASED DISEASE MONITORING SYSTEM (IDMS)

FIELD OF THE INVENTION

[0001] The present disclosure relates to effective, efficient, and economical monitoring of diseases in real-time by integrating patient sensors, cell-phone technology, and the Internet in telemedicine and healthcare infrastructure. In particular, the present disclosure relates to a unique configuration of technology for automated patient-run, real-time monitoring of diseases like asthma and chronic obstructive pulmonary disease (“COPD”), as in spirometry, with interactive and real-time communication among the patient, healthcare providers, medical insurance companies and others via the Internet and mobile communication devices such as personal computers, tablets, and smart phones. The modular configuration of the system allows replacing one sensor module with another to monitor parameters for other ailments such as blood pressure, blood glucose, cholesterol, oxygen saturation, nitric oxide, electrocardiogram (“EKG”), and others.

BACKGROUND OF THE INVENTION

[0002] Improving the level of healthcare requires accurate diagnosis and more frequent monitoring of health conditions. The rising cost of healthcare makes it difficult for patients to achieve such higher levels of healthcare. As patients become more educated about their health, more of the high tech miniaturized electronic technologies become affordably available.

[0003] Achieving higher efficiency, greater frequency of monitoring, higher performance, real-time communication, minimized maintenance and lower costs as well as the reduced burden of carrying various portable devices will greatly enhance healthcare quality. Patients with multiple diseases to be monitored require multiple instruments to be carried, in addition to other consumer devices like cell-phones. A lot of functionality is redundant in the various instruments and devices. One aspect of the present invention aims at efficiently consolidating and utilizing the commonalities of function and redistributing it to achieve optimum cost, ease of use and greater functionality most comprehensively. By way of example, this aspect of the present invention provides an internet-based disease monitoring system (“IDMS”) that can be utilized for most critical and commonly monitored ailments and

conditions. The redistribution is aimed at allocating technical complexities and costs such that all component, process, and system nodes are well integrated for optimum results with the patient end being the most compact and least costly for maximum ease and utility.

[0004] Recently there have been some advancements in the field of Telemedicine such as eHealth, Electronic Medical Record/Electronic Health Record (“EMR/EHR”), Healthcare Informatics and Personal Connected Healthcare, enabling the use of mobile communication devices (such as smart phones) to connect existing medical devices (such as glucometers and pulse oxymeters) to internet-based servers for uploading data to patient records. However, since all the computations are currently conducted on full-function devices, any upgrades to the system require changing the device or physically upgrading it. There is limited ability to integrate the various nodes in the healthcare spectrum. The user is still required to carry each device along with the smartphone, with the inherent redundancy of the device housing, microprocessor, software, display, keypad, electronics, etc.

SUMMARY

[0005] According to one aspect of the present invention, an internet-based disease monitoring system includes a patient-operated device that includes a sensor module and a transmitter module. The sensor produces input signals responsive to a patient condition, and the transmitter is coupled to the sensor and produces output signals corresponding to the input signals produced by the sensor. A mobile communication device (such as a cell phone) is responsive to wireless receipt of the output signals from the patient-operated device and forwards the output signals to a predetermined network address. A remote server at the network address is responsive to the output signals received from the mobile communication device and analyzes the output signals. The remote server further produces analysis signals representing the results of the analysis, and transmits the analysis signals to predetermined recipients associated with the patient-operated device.

[0006] According to another aspect of the invention, an internet-based method for monitoring disease includes producing, via a sensor of a patient-operated device, inputs signals responsive to a patient condition. Output signals corresponding to the input signals are transmitted via a transmitter of the patient-operated device. The output signals are further

forwarded, via a mobile communication device, to a predetermined network address. The output signals are analyzed, via a remote server at the network address, and analysis signals representing the results of the analysis are produced. The analysis signals are transmitted, via the remote server, to predetermined recipients associated with the patient-operated device.

[0007] According to yet another aspect of the invention, a device is directed to determining body function parameters based upon the movement of a patient's breath. The device includes two modules, i.e., a sensor module and a transmission module. The sensor module includes a sensing element and a biasing element. The transmission module includes a light source, a light receiver, a transducer, a processor and a wireless transmission component (such as Bluetooth or ZigBee). The housing forms a flow chamber having a first port in which a human breath is accepted and a second port from which the breath is exhausted. The flow chamber further has an interior surface. The sensing element is movably mounted within the flow chamber and moves bidirectionally in response to pressure from the exhaled breath received from the patient into the first port, as well as to pressure due to the breath inhaled by the patient through the flow chamber. The biasing element resists movement of the sensing element and returns the sensing element to a home position in the absence of any pressure from the exhaled or the inhaled breath. The light source transmits a light beam onto the interior surface of the flow chamber. The light receiver receives light reflected off the interior surface. The receiver is stationary while the source of the light directed onto the interior surface of the flow chamber is mounted for movement with the sensing element as the sensing element is moved within the flow chamber. The transducer is coupled to the light receiver and converts the reflected light into electrical signals. The processor receives and processes the electrical signals, and determines, in response to the pressure from the breath, the extent of the movement of the sensing element. In response to determining the extent, velocity and direction of the movement, the processor further determines the magnitude of the pressure.

[0008] According to yet another aspect of the invention, a device is directed to determining body function parameters based upon the movement caused by a human breath. The device includes a base, a housing, a sensing element, a biasing element, at least one microphone, an acoustic emitter, an acoustic receiver, a transducer, and a processor. The housing is detachably mounted to the base and forms a flow chamber having a first port in

which a human breath is received and a second port from which the breath is exhausted during the exhalation maneuver. The sensing element is movably mounted within the flow chamber and moves in response to pressure from the breath received in or out through the flow chamber. The biasing element resists movement of the sensing element and returns the sensing element to a home position in the absence of any pressure from breath received into the first port. The microphone detects acoustic signals generated by the human breath and the acoustic emitter emits acoustic signals onto the sensing element within the flow chamber. The acoustic receiver receives the acoustic signals reflected off of the sensing element as the sensing element is displaced by the pressure of the breath. The transducer is coupled to the acoustic receiver and converts the acoustic signals into electrical signals based on the extent, velocity (rate of displacement/movement) and direction of the air flow. From this raw data, the server computes the volume, rate of breath flow, and other calculated respiratory function parameters.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] 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.

[0010] FIG. 1 is a diagrammatic illustration of one embodiment of a telemedicine system with various software modules embodying the invention.

[0011] FIG. 2 is a diagrammatic illustration representing the operation of a telemedicine system illustrated in FIG. 1.

[0012] FIG. 3 is a diagrammatical illustration of a sensor and transmitter module (“STM”) for use by a patient.

[0013] FIG. 4 is a flow chart illustrating the operation of the telemedicine system illustrated in FIG. 1.

[0014] FIG. 5 is a flow chart of an APP for enabling a mobile communication device to communicate with an STM.

[0015] FIG. 6 is a diagrammatic illustration of an STM utilizing a movable vane and an optical sensing system for detecting the velocity and magnitude of the vane movement.

[0016] FIG. 7A is a diagrammatic illustration showing a modified STM having an optical light pipe and in which an optical sensor is positioned inside an optical post.

[0017] FIG. 7B is a view of the modified STM shown in FIG. 7A with the sensor and transmission modules in a detached state.

[0018] FIG. 8A is a diagrammatic illustration showing another modified STM without an optical light pipe.

[0019] FIG. 8B is a view of the modified STM shown in FIG. 8A with the sensor and transmission modules in a detached state.

[0020] FIG. 8C is a diagrammatic perspective view of the modified STM shown in FIGs. 8A and 8B

[0021] FIG. 9 is a sectional view illustration of an STM utilizing a movable vane and an acoustic sensing system.

[0022] FIG. 10 is a sectional view illustration of a modified STM utilizing an acoustic sensing system without any moving parts.

[0023] 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 OF ILLUSTRATED EMBODIMENTS

[0024] Although the invention will be described in connection with certain preferred embodiments, it will be understood that the invention is not limited to those particular embodiments. On the contrary, the invention is intended to cover all alternatives, modifications, and equivalent arrangements as may be included within the spirit and scope of the invention as defined by the appended claims.

[0025] Most medical diagnostic or monitoring instruments typically include (1) a front-end sensing module (with a specific sensor and related signal processing circuitry), (2) an electronic system module (composed of keypad, display, microprocessor, etc.), (3) a software module (for analysis of measurements and other parameters, etc.) and (4) a

communication module to connect all the modules to each other and to convey the data or the results of the analysis – often manually – to the physician, the insurance company, etc.

[0026] One aspect of the present invention is directed to reducing a medical instrument, related to personal healthcare monitoring, to its major modules. The front/patient-end module includes a sensor system (for the specific monitoring parameter) that is simple, inexpensive, affordable, and easy to use and carry. The raw data, whether digital or analog, is amplified, conditioned, and converted to a standard signal, which includes a specific device identifier. This data is communicated wirelessly or via a wired connection to a mobile communication device such as a smartphone, a PC, a tablet, a PDA, etc. via an APP downloaded to the mobile communication device. The data is generally in the same form as a typical voice/acoustic or text data signal that is communicated to a mobile communication device, so that the signal is universally applicable to all mobile communication devices (which are primarily designed to transmit and receive voice/acoustic or text data).

[0027] The APP directs the incoming signal to a specific website or network address that recognizes the device and automatically analyzes the signal. The results are transmitted from the server to various locations in relevant formats – to the patient, the clinic/hospital, electronic medical record (“EMR”) repository, electronic health record (“EHR”) repository, the physician, the insurance company, etc. With the “whole” system approach illustrated by features of the present invention, including internet-based disease monitoring system described below, the cost, bulk, and complexity of the system is consolidated and redistributed away from the patient-end toward the server and infrastructure end, where it amounts to a small increment and is more readily tolerated and afforded.

[0028] Ongoing relative costs are also redistributed in the form of appropriate subscriptions. For example, simple text/internet link subscriptions are available for the patient and data-access subscriptions are available to the clinic, physician, insurance company, etc. The system also allows a direct video link between the patient and the physician, for example, via cell-phone cameras or tablet or PC webcams for a more intimate, personalized, and clinically useful assessment of the patient’s condition.

[0029] Turning to the drawings, FIG. 1 illustrates a system 100 in which a patient 102 uses a spirometer 104 to monitor the patient’s respiratory condition. The patient breathes into the spirometer 104, both inhaling and exhaling, and the spirometer automatically detects

the displacement and rate (volume and velocity) of air movement through a flow chamber in response to the patient's breathing. The spirometer 104 also produces electrical output signals representing the detected parameters (e.g., volume and velocity), and broadcasts those output signals into a near-field region surrounding the spirometer. In the illustrative system 100, those near-field signals are detected and received by the patient's smart phone 106, which includes an application ("APP") for detecting such signals and transmitting them to predetermined destinations via a network 108 such as the Internet.

[0030] In FIG. 1, the potential destinations illustrated are a remote server 110, a health insurance company computer 112, a clinic 114, and/or a physician smart phone 116. The specific destinations to which results and reports are forwarded are selected by the caregiver (physician, clinic/hospital) and saved in the central cloud-based server 110 where computations are conducted, for automatic processing and authenticated closed-loop for credibility, not subject to patient's accidental or willful changes. Alternatively, the patient's smart phone 106 may be used to preselect, via settings made in the patient's smart phone 106, the specific destinations to which signals received from the spirometer 104 are to be forwarded. The settings are selected via a display generated by the APP in a settings window of the patient's smart phone 106.

[0031] The illustrative system 100 includes three software modules: a front-end sensor-transmitter module ("STM") 120A, a mobile communication and display module ("MCDM") 120B, and an internet-based server for data processing and distribution module ("DPDM") 120C. The STM 120A includes a precise sensor to generate raw signal data and circuitry and/or software for signal conditioning. The raw signal data is optionally encrypted (e.g., SSL) and transmitted wirelessly (e.g., Bluetooth or ZigBee at 2.4 GHz). The STM 120A transmits a device ID with encrypted patient-specific header/demographics, and raw sensor data in digital/text form to the patient's smart phone 106.

[0032] One example of the STM 120A is a pocket electronic spirometer ("PES") for measuring and monitoring pulmonary function, as described in U.S. Pat. No. 5,816,246. As described in more detail below, the sensor may be a simple, low cost, but highly precise (1000–1500 dpi or even greater resolution) device, such as a light-emitting diode ("LED") device or laser-based device. In another example, the sensor is the same as that used in a Bluetooth mouse.

[0033] The MCDM 120B includes two specific mobile/cell-phone APPs – one for the patient's smartphone 106 and another for the physician's smart phone 116. The APPs are custom written in mobile java or other format for the smart phone 116 to connect to the remote server 110, and to transmit the raw data to the remote server 110 for analysis, distribution and/or storage.

[0034] The DPDM 120C includes the remote server 110, server software modules, sensor-specific computational modules, reporting modules, database archiving (basic web-page, spirometry data, or full interactive web-sys for multiple sensor systems) and PC software module for insurance companies 112, clinics and medical facilities 114, pharmacies 116, etc.

[0035] A physician normally prescribes the STM 120A to the patient after initial testing at a clinic or hospital and having determined a specific diagnosis and established norms for the patient. The STM 120A is initiated at the physician's office, with basic patient information and is assigned a record number as a basic identifier for the patient and his/her diagnosis/condition, type of test, etc. The physician also sets certain alarms specific to the patient's condition to serve as reminders or warning alerts that immediate physician attention is required.

[0036] Desired parameters are calculated and formatted on the remoter server 110 in various formats for the patient, the clinic record, the physician, EMR/EHR database, medical insurance company, etc. The parameters are further optionally formatted in any other desired format previously identified and saved on the remote server 110. The remote server 110 automatically directs data in appropriate formats to appropriate nodes of the system 100. For example, the patient receives the most simplified version appropriate for self-monitoring and management of the disease or condition with any applicable medical advice based on the results. Detailed data is transmitted to the clinic, appropriate formatted data is transmitted to the EMR/EHR database, and financial and reimbursement related data is transmitted to the insurance company in an appropriate billing format. If the patient parameters are in the warning alarm range, appropriate personnel are alerted and alert messages are automatically transmitted to the clinic/hospital 114, the physician's smart phone 116 and the patient's smart phone 106.

[0037] Referring to FIG. 2, the system 100 is further interconnected in a hub-and-spoke configuration such that each component and/or device is directly and/or indirectly communicatively coupled with one or more of the other components and/or devices. For example, the patient's smart phone 106 (e.g., a cell phone) communicates directly with the spirometer 104 and the Internet 108, and is optionally also connected to an E-Health server 110. Similarly, a patient tablet 111 communicates directly with the spirometer 104 and is optionally connected to the E-Health server 110 and/or computers of medical insurance companies 112. The patient tablet 112 may provide the patient additional options and/or a more user-friendly interface than the patient's smart phone 106.

[0038] Referring to FIG. 3, an illustrative STM 130 includes several sub-modules and/or components, including a flow-chamber mouthpiece 132, a flow-chamber housing 134, a spring-loaded vane 136, a digital signal processor ("DSP") 138 (which is positioned at a convenient point on a circuit board), an optical or acoustic sensor system 140, and a transmitter system 142. In general, a patient blows air into the flow-chamber mouthpiece 132, forcing air into the flow-chamber housing 134. The forced air causes movement of the spring-loaded vane 136, the movement being sensed and tracked by the sensor system 140. The sensor system 140 produces signals that are optionally conditioned and/or digitized prior to being transmitted by the transmitter system 142. The processor 138 optionally performs required tasks associated, for example, with the conditioning, digitizing, and/or transmission of the signals. The STM may optionally have a secure feature to ensure only the patient-owner may be able to use the device, such as in combination with the patient's own paired smart phone, to automatically transmit test data.

[0039] The sensor system 140 includes one or more patient sensors, signal conditioning circuitry, and/or digitization circuitry. The sensor system 140 senses, for example, a patient condition measured by a spirometer, an OEM blood glucose meter, or a cholesterol monitor. The sensor system 140 further senses, by way of a further example, a patient condition associated with blood oxygen saturation ("SpO2"), nitric oxide levels, and other conditions. The flow chamber module may be replaced by specific modules for other disease conditions to connect with the transmitter module to complete the STM patient device.

[0040] The transmitter system 142, includes circuitry and/or components, for example, for signal amplification and/or encryption. The transmitter system 142 further includes circuitry and/or components for Bluetooth, Wi-Fi, and/or ZigBee transmissions. As such, the transmitter system 142 can transmit a full range of digital and/or analog data received from a variety of sensors.

[0041] Referring to FIG. 4, a method of monitoring a patient condition includes step 140 in which a patient uses the STM at a physician's office to initiate a telemedicine system. Prior to initiating the telemedicine system, the physician tests the patient's respiratory functions to establish and record the patient's baseline spirometry values. To do so, the physician may use a clinic-based IDMS-spirometry module with a disposable breath flow chamber or the patient's own IDMS-spirometry module and flow chamber.

[0042] Then, the STM, which has a unique serial number embedded for identifying the STM, is initialized at the physician's office. For example, the initiating includes setting a patient ID and setting one or more alarms as well as the specific destinations where the results and/or reports are to be automatically transmitted. The STM is connected with a master clinic-based system associated with the physician and key patient demographics and health information is inputted from the clinic-based system. The information is inputted, for example, by bar code scanning or via a user interface. After relevant data is downloaded, the data is encrypted and embedded in the patient's STM. The physician updates the information as and when needed. Basic patient demographics and health information embedded in the STM typically includes one or more of the following information: (a) a patient identification number; (b) a name, address, and telephone number for the patient; (c) patient gender and age; (d) patient diagnosis; (e) physician name and identification number; (f) patient's insurance carrier and number; (g) patient's preferred pharmacy and contact information for prescriptions; and/or (h) smoking habits.

[0043] At step 142, the patient uses the STM at specified times, e.g., when needed (depending on the patient's condition) or when prompted. For example, the physician instructs the patient to use the STM every morning to monitor the patient's health condition.

[0044] At step 144, the sensor system of the STM produces a signal indicative of a patient condition and, in response, the sensor system and/or the transmitter system of the STM condition, encrypt, convert to voice and/or data, and transmit the signal wirelessly or by

wire. At step 146, a patient's mobile device (e.g., a smart or cell phone) receives the signal and logs onto a dedicated website server. The server authenticates, at step 148, the patient and/or the mobile device, and receives, processes, and transmits results of the patient condition to the physician and to the patient mobile devices, as well as to all other identified destinations.

[0045] At step 150, the results are transmitted in the form of data to a clinic where the patient is registered, to other medical services for interpretation, to the patient's medical insurance company, and/or to a HER medical records database. At step 152, the physician is alerted, for example, by a smart phone and/or a PC if test data reaches set critical limits. The physician connects with the patient via phone and/or video link at step 154 to discuss the results of the monitored condition and advice.

[0046] Referring to FIG. 5, a mobile APP is directed to monitoring a patient condition and includes, at step 160, initiating a medical test. The mobile device (e.g., cell phone) is awakened in response to receiving an incoming wireless signal (e.g., received via Bluetooth or ZigBee) from the STM upon the patient conducting the medical test. Data representative of the medical test is received by the mobile device.

[0047] At step 162, the patient mobile device connects to an IDMS web-based server via an incoming data port. At step 164, the mobile device receives a confirmation signal from the IDMS server. At step 166, the mobile device forwards the data to the IDMS server. The data is optionally forwarded as encrypted raw data.

[0048] At step 168, the mobile device is awakened by a signal from the IDMS server that incoming results are being or have been sent by the IDMS server. For example, the mobile device receives a confirmation text message from the IDMS server that the results are completed.

[0049] At step 170, the mobile device alerts the patient that the results have been received. For example, the mobile device generates an audio and/or visual alert in the form of a text message to alert the patient.

[0050] At step 172, the mobile device displays the results in a default test data format or in a format specified by a physician. The displaying can be, for example, as simple as opening a text message to view the results.

[0051] At step 174, the mobile device facilitates a communication connection between the patient and the caregiver (e.g., the patient's physician, clinic, or hospital). For example, upon selection of an icon on a screen of a smart phone or a button on a cell phone keypad, the patient connects with the caregiver and talks or leaves a voicemail or text message. If a voicemail or text message is left with the caregiver, subsequently, an incoming call or message from the caregiver is signaled on the mobile device, allowing the patient to receive and respond after authenticating by the patient. Patient log-in information may be enabled or disabled, depending on selected security preferences. Optionally, a unidirectional or bi-directional video communication is initiated with the caregiver. The video communication may include turning on respective cameras on mobile devices for the patient and/or the caregiver.

[0052] At step 176, the mobile device provides options for patient selection of other environmental data and/or health information. For example, the mobile device allows selection of icons for pertinent environmental data and/or other important health information and/or health tips. For example, based on the location of the mobile device (e.g., using GPS coordinates), the options may include information related to ozone level, pollution index, smog level, and heat index acquired from public web sites and/or the server 110.

[0053] At steps 178, 180, the mobile device captures/receives and displays the selected environmental data and/or health information. The displaying of the data/information is presented upon demand and/or with test results.

[0054] By way of background, spirometry is measurement of a patient's respiratory condition and capacities. As such, a typical spirometer is an instrument used to measure the inspiratory and expiratory performance of the patient's lungs. Most prior spirometers utilize pressure transducer-based sensors called pneumotachometers to measure pressure variations in a tube of a fixed volume as the breath flows through the tube, and to calculate several flow and volume-based respiratory parameters from the measured pressure variations. Another common previous technique utilizes a turbine inside a breath flow tube. The flow of breath turns the turbine, and the rotation of the turbine's fins is measured by corresponding interruption of an optical beam. These prior techniques require the breath to flow directly over the measurement mechanism, further requiring the use of disposable filters, disposable pressure transducers and/or interfaces to prevent bacterial contamination and

clogging of the system due to warm and moist breath of the same or multiple patients. These additional elements affect accuracy of the measurements, requiring constant corrections in the software, and adding additional complexity, bulk and costs to prior spirometer systems. Thus, these systems also require frequent calibrations.

[0055] Improved spirometers described below eliminate all the moving parts on the measurement side, other than the vane, making the system simpler, more rugged, and more economical to produce and to own. These improvements allow complete elimination of all moving parts (gears, encoder, etc.) from a main housing. For improved optical configurations described below, the only remaining moving part is the vane inside the flow chamber. For an improved acoustic configuration described below, even the vane is eliminated, leaving no moving parts in the entire system.

[0056] Utilizing precision high tech, but extremely low cost, optical sensing components, as used in an optical/laser mouse for cursor control on a computer, the system further improves accuracy through higher resolution. The system functions in much the same way as an optical/laser mouse operates, thus improving resolution, accuracy, response time and reliability, as well as producing digital signal. This further simplifies the system by eliminating the need for analog-to-digital conversion circuitry and also reducing the potential errors and cost.

[0057] Referring to FIG. 6, and by way of a specific example, an STM is in the form of a spirometer 200 with a flow-chamber 202. The flow-chamber 202 includes an encased spring-loaded vane 206 mounted for pivoting bidirectional movement about an axis 215 in the central portion of the flow chamber, defined by a stationary shaft or stub, in response to the patient's breathing in and out through the flow chamber. According to one example, the flow-chamber 202 is a circular washable and/or disposable plastic flow-chamber housing having inlet and outlet openings to accommodate a patient's breathing through the chamber.

[0058] The spirometer 200 includes a light source 208 coupled to a first optical light pipe 210 that extends through the spring-loaded vane 206 so as to emit light from the free end of the vane 206 onto the wall of the flow chamber 202. Light reflected by the wall of the flow chamber is picked up by the end of a second optical light pipe 214 that extends through the vane 206, parallel to the first light pipe 210, to an image sensor 212 such as a

charge-coupled device (“CCD”) image sensor or a complementary metal-oxide-semiconductor (“CMOS”) image sensor. The image sensor 212 tracks bi-directional displacement, caused by breath expiration and/or inspiration, of the spring-loaded vane 206 inside the flow-chamber 202. The image sensor 208 transmits the image to a DSP (such as DSP 138 illustrated in FIG. 3) for analysis.

[0059] An initial cracking-point from a resting position of the spring-loaded vane 206, in either direction, sets a system calibration reference point. According to one example, a spirometer has been constructed utilizing PC and computer mouse components and a custom software application in Visual Basic, and a full breath displacement has been captured with a 10 milliseconds sampling rate, with captured data being imported into an Excel spreadsheet in which a flow-volume loop and a volume-time graph were developed.

[0060] Changes between one image frame and a next image frame are processed by the image processing part of the DSP 138 and translated into movement on two axes. For example, the ADNS-2610 optical mouse sensor manufactured by Agilent Technologies processes 1512 image frames per second, with each image frame being a rectangular array of 18x18 pixels and each pixel sensing 64 different levels of gray. The DSP 138 detects patterns in the images and recognizes how those patterns have moved since the previous image. Based on the change in patterns, the DSP 138 determines how far the vane 206 has moved and transmits the corresponding coordinates to the microprocessor 232. This occurs hundreds of times each second, making the measurement very smooth and is able to detect any aberration in the breathing pattern to track the breath precisely.

[0061] Instead of using a LED-based emitter 212, an IR laser diode is beneficial because it uses a laser beam with which the measurement is even more precise, giving better response times and tracking. A single-chip optical mouse sensor like STMicroelectronics VT 5365 is optionally used for wireless and Bluetooth applications. This single-chip economical solution provides an internal microprocessor and minimal external circuitry, low power requirement, long battery life, operation with up to 10,000 frames per second, and tracking at up to 40 inches per second.

[0062] Another even more effective optical sensor system is a compact (6.8 mm square, 3.86 mm high) Philips PLN2033 “Twin-Eye” laser sensor based on Laser Doppler technology. It is a high-precision, ultra-fast, low-power, small-sized, single-component,

laser-based tracking device for use in input and navigation devices like professional PC mice, gaming and CAD applications as well as graphical workstations. The PLN2033 “Twin-Eye” laser sensor offers accurate performance over a wide range of speeds and accelerations on virtually all light scattering surfaces covering the demands for e.g. gaming and office applications. It measures changes in position by detection of the scattered coherent laser light that is reflected by a surface, and mathematically by on-chip logic and software, determining the direction and magnitude of the movement up to 3.8 meters per second for each axis (150 inches per second). It is capable of measuring extremely accurately with a re-programmable resolution ranging from 100 CPI to 6400 CPI. The resolution can be re-programmed with an accuracy of 1 CPI.

[0063] Referring to FIGs. 7A and 7B, modified embodiments of the spirometer 200 illustrated in FIG. 6 utilize a combination light emitter/image receiver 216 such as the Philips “Twin-Eye Laser” sensor (PLN2023) or Philips “Laser Doppler” sensor. This combination device 216 permits the use of a single light pipe 210 that both transmits light from the device 216 to the wall of the free end of the vane 206, and picks up light reflected from the wall of the flow chamber 202 and transmits that light back to the device 216. In FIG. 7A, the device 216 and the adjacent end portion of the light pipe 210 are aligned with the axis 215. In FIG. 7B, the device 216 and the light pipe 210 are aligned with an axis 217 that extends diagonally through the vane 206 so as to emit light from the top edge of the vane 206 onto the upper wall of the flow chamber 202. Light reflected back from the upper wall of the flow chamber light is picked up by the light pipe 217 and transmitted back to the device 216. According to one example, the light pipe 217 and the device 216 are oriented at an angle of about 15-30 degrees from a vertical post receiver axis 215.

[0064] Referring to FIGs. 8A-8C, another modified embodiment of the spirometer 200 illustrated in FIG. 6 utilizes direct pick-up of displacement of the spring-loaded vane 206 without the use of any light pipes. In this embodiment, the combination light emitter/image receiver 216 is mounted on a base 204 adjacent the lower surface of a disc 218 formed as an integral part of the vane 206 so that the disc moves with the vane, thus providing relative movement between the disc and the stationary device 216.

[0065] Regardless of the particular optical configuration, thousands of successive pictures of the surface area immediately in front of the image sensor 208 may be captured,

with or without a respective optical light pipe conduit. Based on the thousands of images that the image sensor 208 transmits to the DSP 138 for analysis, the DSP 138 detects both patterns and movement of the vane 206. As such, the DSP 138 determines if the vane 206 has moved, and if so, the displacement, speed, and direction of the movement. In turn, the speed and movement of the vane 206 in the fixed space within the flow-chamber 202, against the inspiratory and expiratory breath, translate to volume and flow measurements of spirometry.

[0066] The acoustic implementations are preferably integrated into the full system in the same way as the optical implementations described above (i.e., acoustic sensors instead of the optical ones). Thus, they would also include the sensor and the transmission modules and wirelessly communicate the raw data via cell phone to the cloud/web-based server for analysis and distribution to all the nodes identified earlier. Optionally, both the optical and the acoustic implementations can have a microprocessor in the main housing (as described here) that may send the result to the patient cell-phone – and from there still be able to send them to the web-based server to utilize the central monitoring, distribution and record keeping as described earlier.

[0067] Referring to FIG. 9, an acoustic implementation includes a pocket spirometer 220 with a mouthpiece 222 into which a patient blows a breath of air A to drive a vane 224 (comprising rotatable vane element 224A) in a flow chamber 226. The breath of air creates pressure that causes movement of the vane 224, displacing the vane 224 from an initial position. The movement of the vane 224 is sensed by an acoustic sensor system having an acoustic emitter 234 and a microphone 236. The acoustic sensor system utilizes a vane surface to reflect emitted sound (similar to a Doppler effect) as the vane 224 is displaced by the flow of breath air A. The position of the vane 224 is determined and provides a basis for calculating volume and flow rate within the flow chamber 226.

[0068] The acoustic sensor system is positioned external to the flow chamber 226 and within a main housing of the spirometer 220 in which other electronic components are mounted. The acoustic sensor system is coupled to the flow chamber 226 via a thin-walled window to maintain a complete bacterial-free separation between the patient's breath and the acoustic sensor system. The flow chamber 226 is optionally detached from the main housing containing electronic components and rinsed for re-use.

[0069] The microprocessor 232 provides results to a display of a device, such as an LCD display of a patient mobile device, and stores the results into an associated memory of the device. Upon storing the results to the device memory, the results can optionally be erased from the spirometer memory 230. Optionally, the results are stored on other memory devices, including memory cards and/or personal computers.

[0070] At the completion of a test, the microprocessor 232 further determines a highest value reached on an expiratory flow curve and displays that value as a Peak Expiratory Flow Rate (“PEFR”). Based on a plot of a flow-time curve, a Forced Expiratory Volume in one second (“FEV1”) can be easily calculated. Other parameters such as Forced Vital Capacity (“FVC”), Mid-Expiratory Flow Rate, (“FEF 25-75”), Forced Inspiratory Flow Rate (“FIVC”) at 50% (“FIF 50”), and other parameters are similarly measured from the stored data.

[0071] Referring to Fig. 10, another acoustic implementation eliminates the vane 224 such that the spirometer 220 does not require any moving parts. In this streamlined flow chamber configuration, one or more highly sensitive microphones 250, 252 are positioned externally across a thin-walled window 253 in the flow chamber 226 to maintain a bacterial-free separation. The inside configuration of the flow chamber includes a ridge 254 in the air flow path that enhances the sound of breath blowing over it.

[0072] The microphones 250, 252 are placed closest to the ridge 254 to maximize the sound quality, which is further enhanced by a conical configuration leading to the ridge. The microphones capture an acoustic signal generated by the patient’s breath as it flows against this geometrically optimized internal configuration of the flow chamber.

[0073] An acoustic pattern generated by the flowing breath correlates to the flow and volume inside the fixed space of the flow chamber for both expiration and inspiration. The simplified flow chamber is detachable and optionally a disposable or a reusable (e.g., rinseable) unit. Two microphones, instead of a single microphone, are helpful in determining the direction of flow corresponding to expiration and inspiration.

[0074] While particular embodiments and applications of the present invention have been illustrated and described, it is to be understood that the invention is not limited to the precise construction and compositions disclosed herein and that various modifications,

changes, and variations can be apparent from the foregoing descriptions without departing from the spirit and scope of the invention as defined in the appended claims.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A medical device comprising:

a flow chamber housing, the flow chamber housing comprising a first port, a second port, and an interior surface, wherein the interior surface is exposed to air when air passes through the first port and the second port as inspiratory and expiratory breath flow;

a spring-loaded vane mounted to the interior surface for pivoting bidirectional movement about an axis in a central portion of the flow chamber housing, the spring-loaded vane configured for displacing in response to the air passing through the first port and the second port;

a disc coupled to the spring-loaded vane, wherein the disc is configured to move when the spring-loaded vane displaces in response to the air passing through the first port and the second port; and

a sensor transmission module housing detachably coupled to the flow chamber housing, the sensor transmission module housing comprising:

a light source coupled to the sensor transmission module housing, wherein the light source is configured for emitting light onto a surface of the disc;

an image sensor coupled to the sensor transmission module housing and a digital signal processor, wherein the image sensor is configured for receiving reflected light from the surface of the disc;

the digital signal processor operatively coupled to at least one processor, the digital signal processor configured for receiving images from the image sensor and determining coordinates corresponding to displacement of the spring-loaded vane based on changes in the received images from the image sensor; and

the at least one processor operatively coupled to a transmitter, the at least one processor configured for converting the coordinates received from the digital signal processor into a data package including a specific device identifier associated with the medical device, encrypting the data package, and transmitting, via the transmitter, the encrypted data package to a mobile communication device for further transmission to a secure server for decryption and analysis, wherein the data package is formatted as text data.

2. The medical device of claim 1, wherein the light source is a light-emitting diode.
3. The medical device of claim 1, wherein the light source is a laser diode.
4. The medical device of claim 1, wherein the light source and the image sensor are a single device.
5. A medical device comprising:
 - a mouthpiece in fluid connectivity with a flow chamber housing;
 - a spring-loaded vane mounted for pivoting bidirectional movement about an axis in a central portion of the flow chamber housing, the spring-load vane comprising at least one light pipe for transmitting light from a light source to an interior wall of the flow chamber housing;
 - and
 - a sensor transmission module housing detachably coupled to the flow chamber housing, the sensor transmission housing comprising:
 - the light source operative for emitting light onto an interior wall of the flow chamber housing via the at least one light pipe;
 - an image sensor coupled to a digital signal processor, wherein the image sensor is configured for receiving reflected light from the interior wall of the flow chamber housing;
 - the digital signal processor operatively coupled to at least one processor, the digital signal processor configured for receiving images from the image sensor and determining coordinates corresponding to displacement of the spring-loaded vane; and
 - the at least one processor operatively coupled to a transmitter, the at least one processor configured for transmitting, via the transmitter, text data comprising the determined coordinates and an identifier associated with the medical device to a mobile device for further transmission to at least one server for processing.
6. The medical device of claim 5, wherein the light source is a light-emitting diode.

7. The medical device of claim 5, wherein the light source is a laser diode.
8. The medical device of claim 5, wherein the light source and the image sensor are a single device.
9. The medical device of claim 5, wherein the light pipe is aligned with an axis that extends diagonally from a bottom of the spring-loaded vane to a top of the spring-loaded vane.
10. The medical device of claim 5, wherein the at least one processor is configured for receiving the determined coordinates from the digital signal processor, converting the determined coordinates to text data, encrypting the text data, and creating a data package comprising the encrypted text data and the identifier associated with the medical device.
11. The medical device of claim 10, wherein the at least one server is configured for analyzing the text data based at least in part on the identifier associated with the medical device.
12. A system comprising:
 - a sensor transmission module housing configured for detachably coupling to a medical device, the sensor transmission module housing comprising:
 - a sensor for receiving information from the medical device, the sensor coupled to the sensor transmission module housing and a digital signal processor;
 - the digital signal processor operatively coupled to at least one processor, the digital signal processor configured for receiving the information from the sensor and converting the information received from the sensor to digital data; and
 - the at least one processor operatively coupled to a transmitter, the at least one processor configured for encrypting the digital data and converting the digital data into a data package, the data package including a device identifier associated with the medical device, and transmitting, via the transmitter, the data package to a mobile device for further transmission to a server for decryption and analysis of the digital data based at least in part on the device identifier.

13. The system of claim 12, wherein the sensor is an image receiver for capturing images based on changes in light within a flow chamber of the medical device.
14. The system of claim 13, wherein the sensor transmission module housing further comprises a light-emitting source.
15. The system of claim 14, wherein the light-emitting source is a light-emitting diode.
16. The system of claim 14, wherein the light-emitting source is a laser diode.
17. The system of claim 14, wherein:
 - the medical device comprises a disc coupled to a vane configured for pivotal displacement in response to air passing over the vane; and
 - the image receiver detects changes in a location of the vane when the vane is pivotally displaced based on movement of the disc.
18. The system of claim 12, wherein:
 - the sensor is at least one microphone for receiving sound waves within the flow chamber;
 - and the medical device comprises a ridge shaped for enhancing a sound of air passing over the ridge.
19. The system of claim 18, wherein the medical device further comprises a conical configuration leading to the ridge.
20. The system of claim 19, wherein the sensor comprises a first microphone positioned on a first side of the ridge and a second microphone positioned on a second side of the ridge for determining a direction of the passing of air over the ridge.

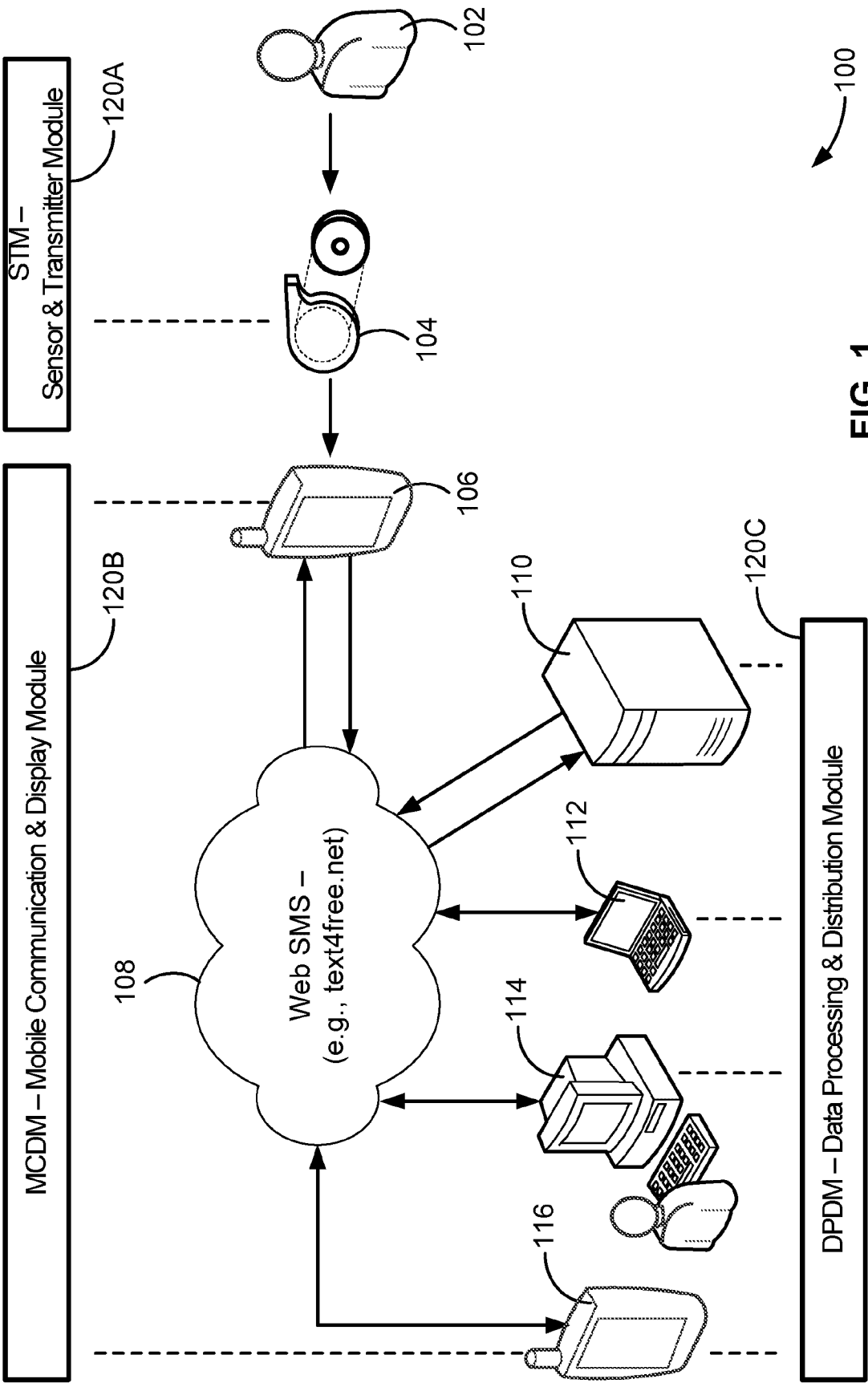


FIG. 1

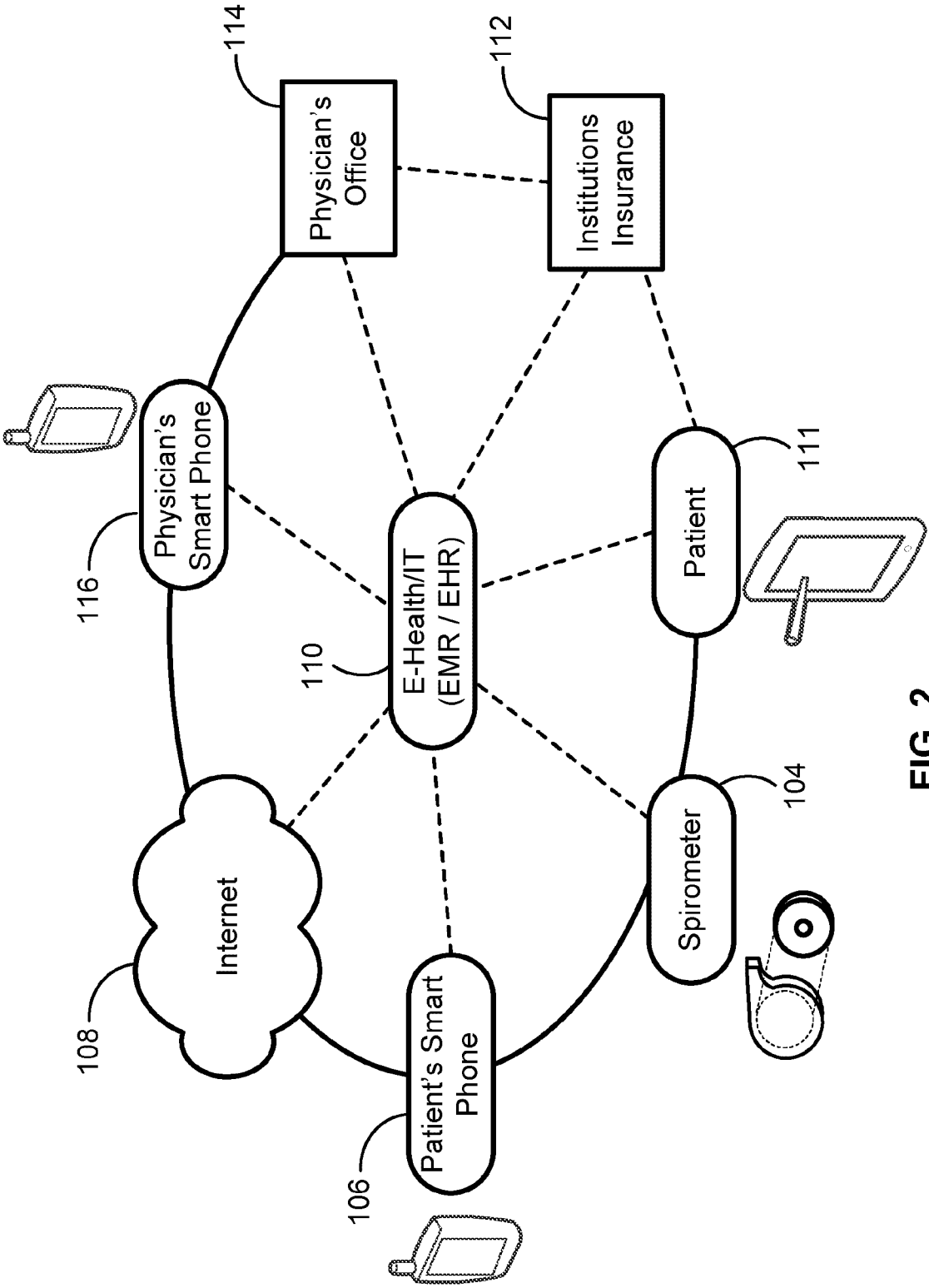


FIG. 2

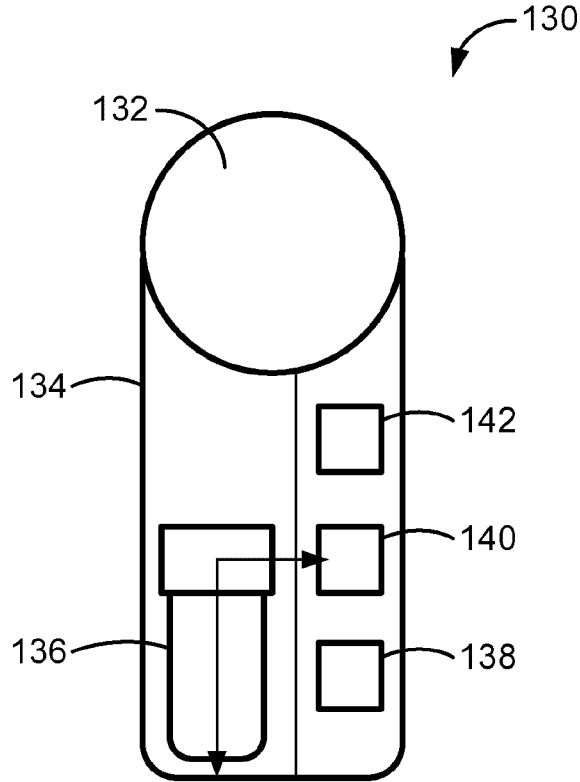


FIG. 3

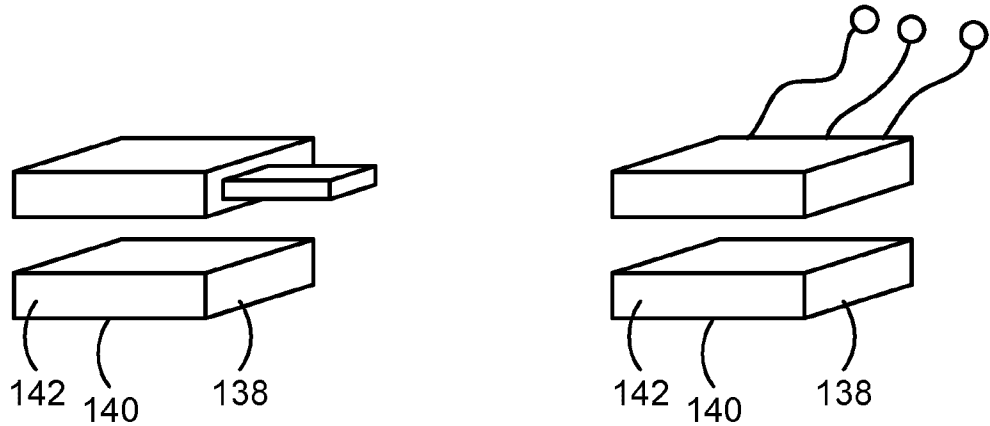


FIG. 3A

FIG. 3B

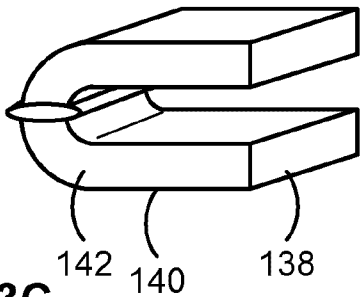


FIG. 3C

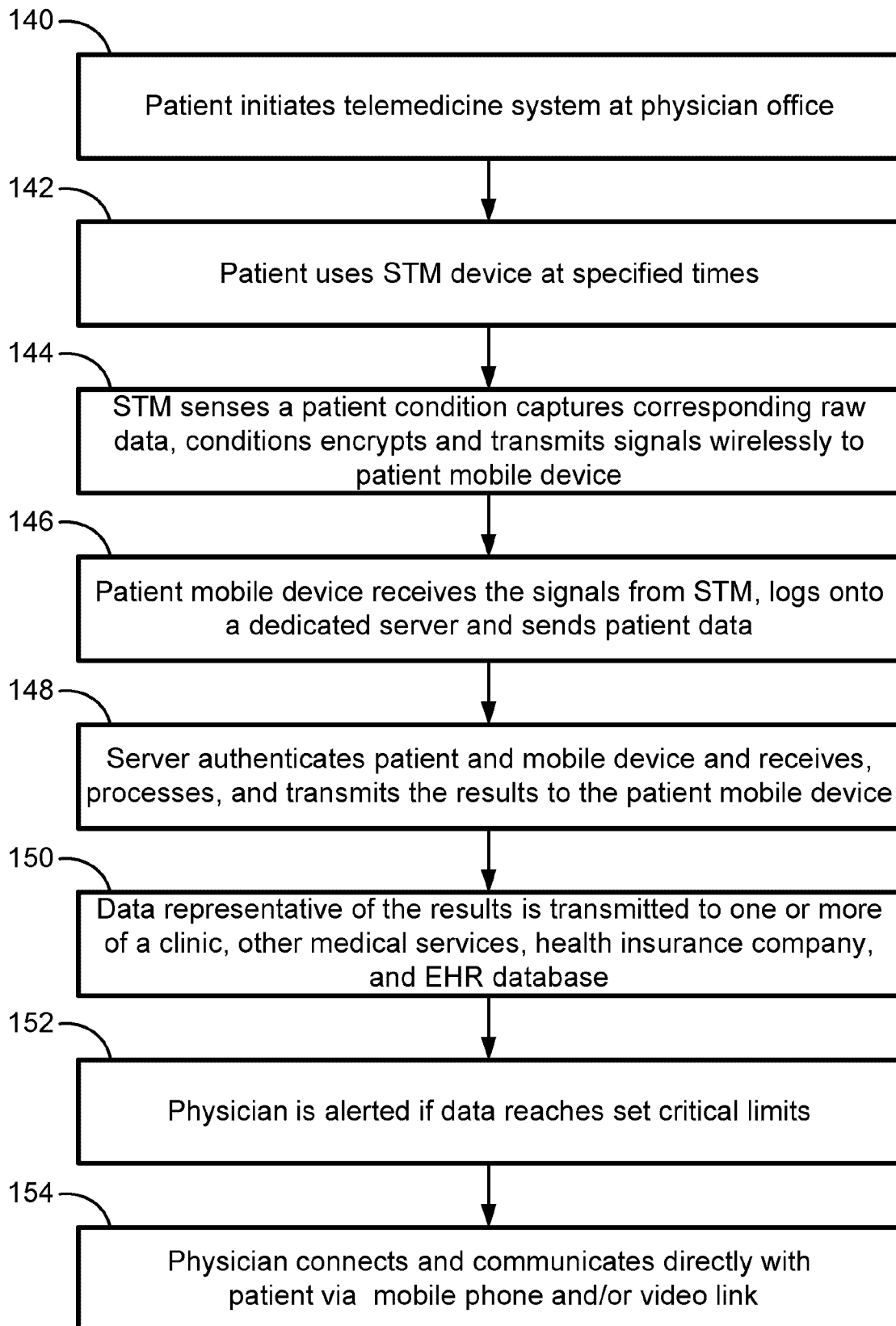
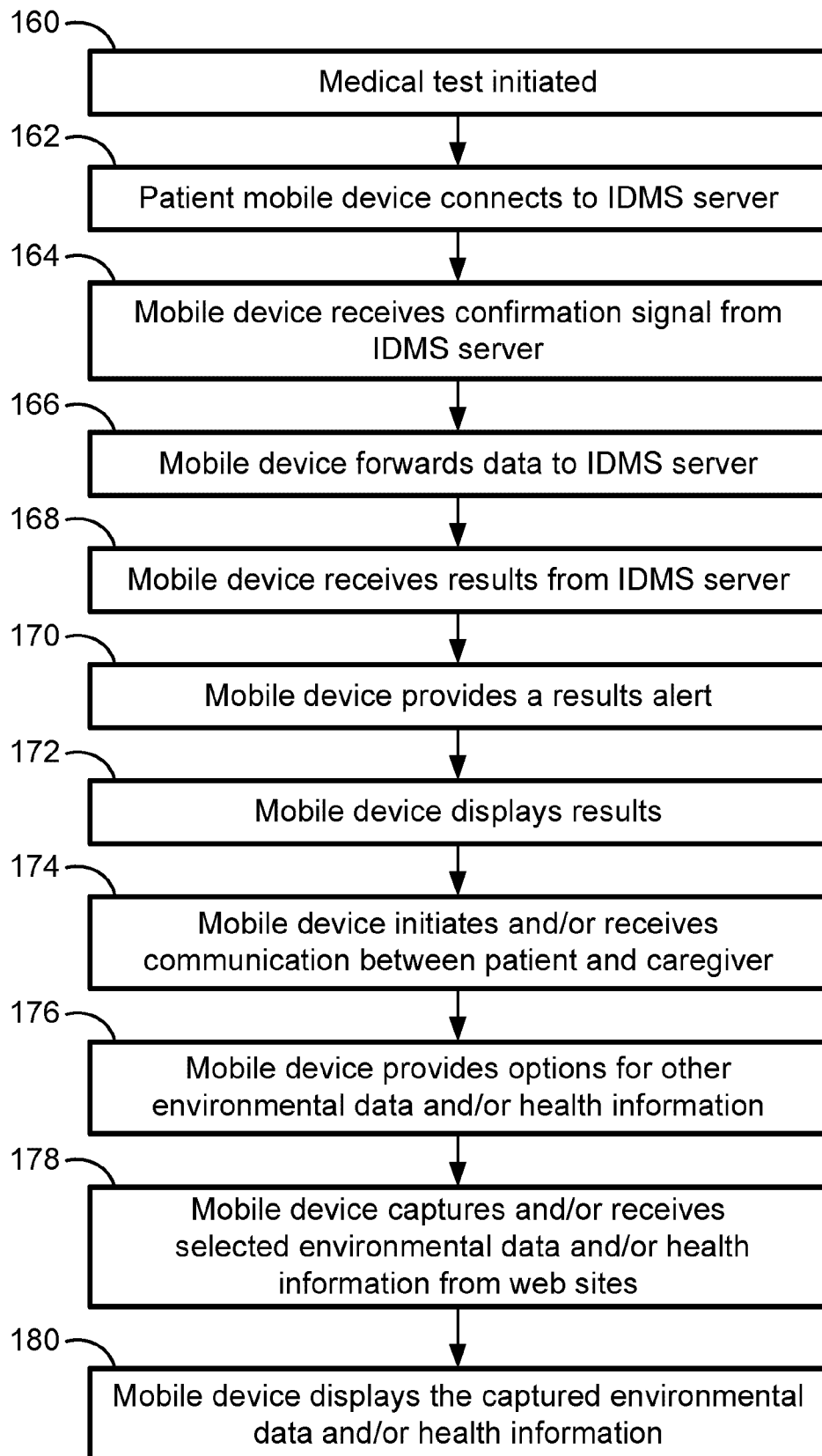
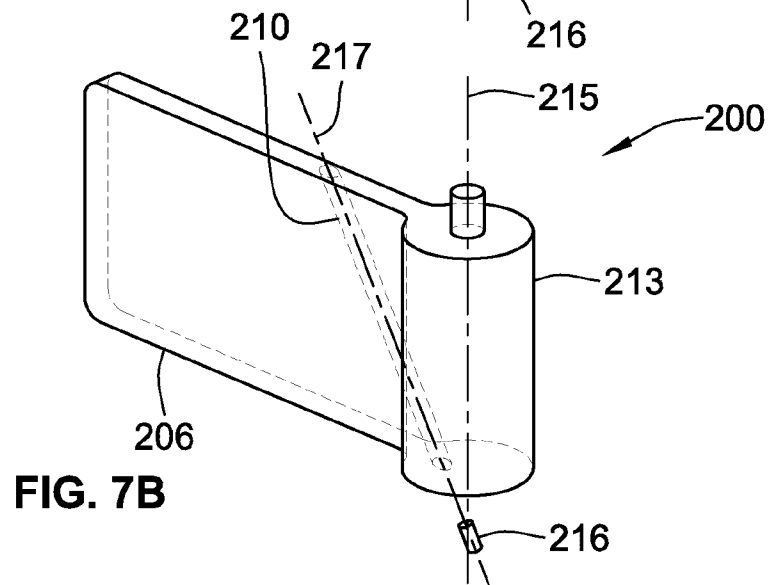
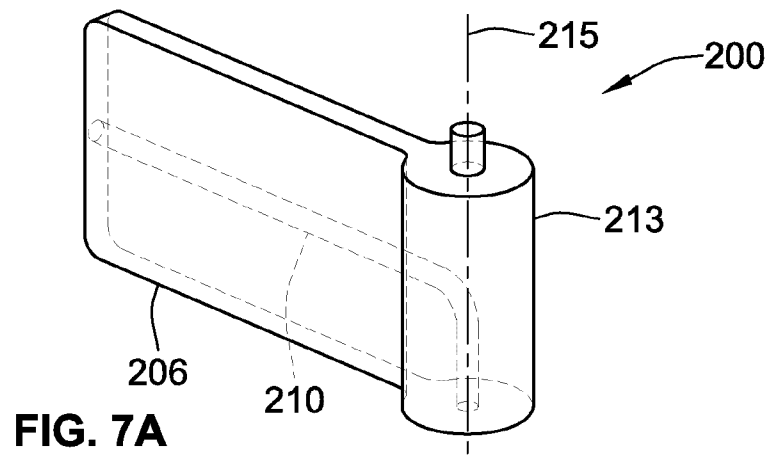
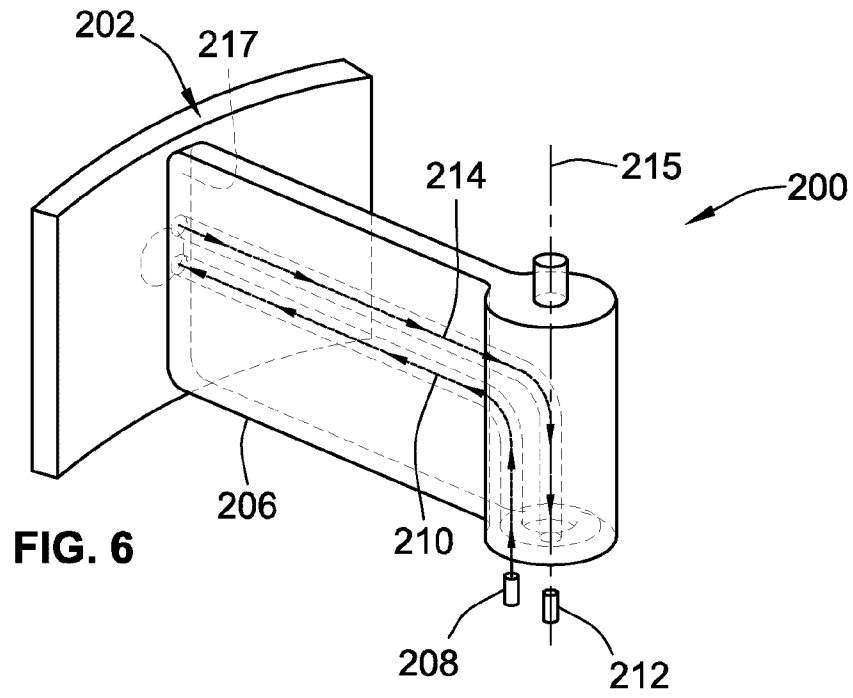


FIG. 4

**FIG. 5**

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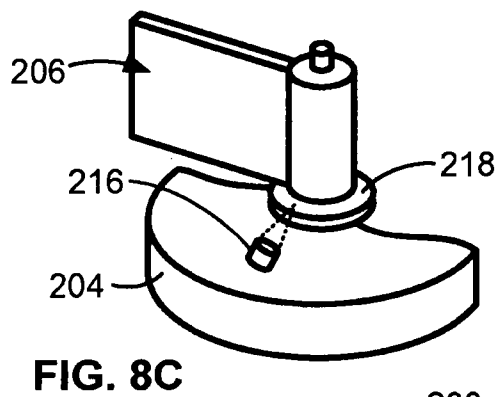
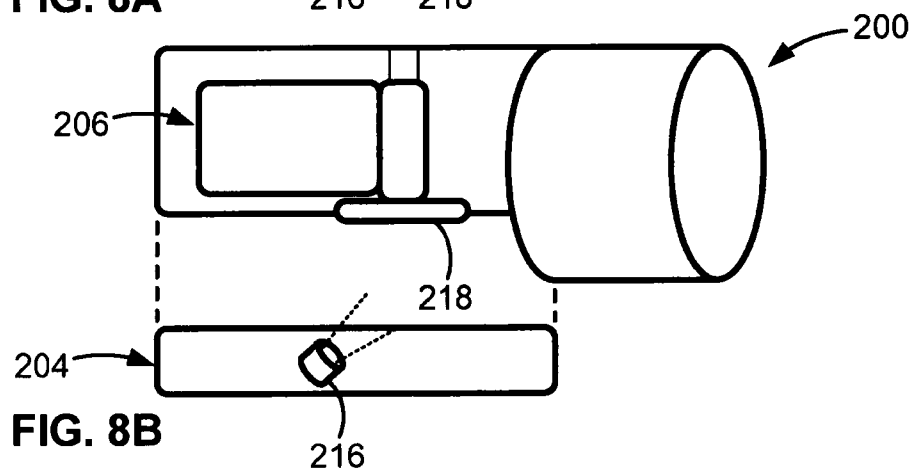
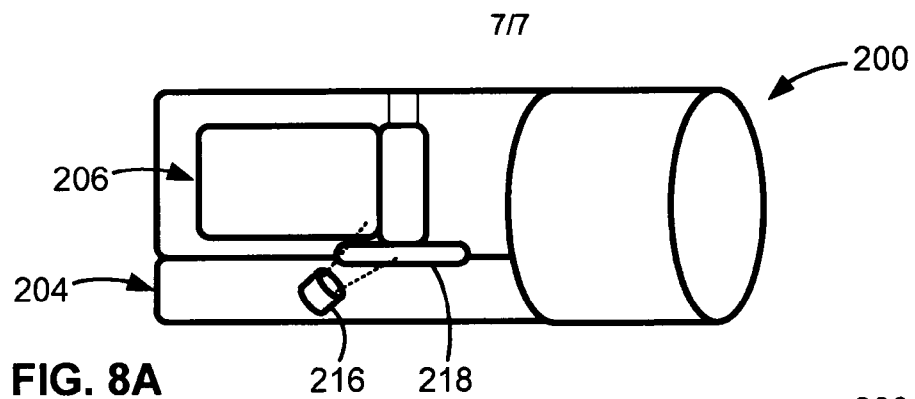
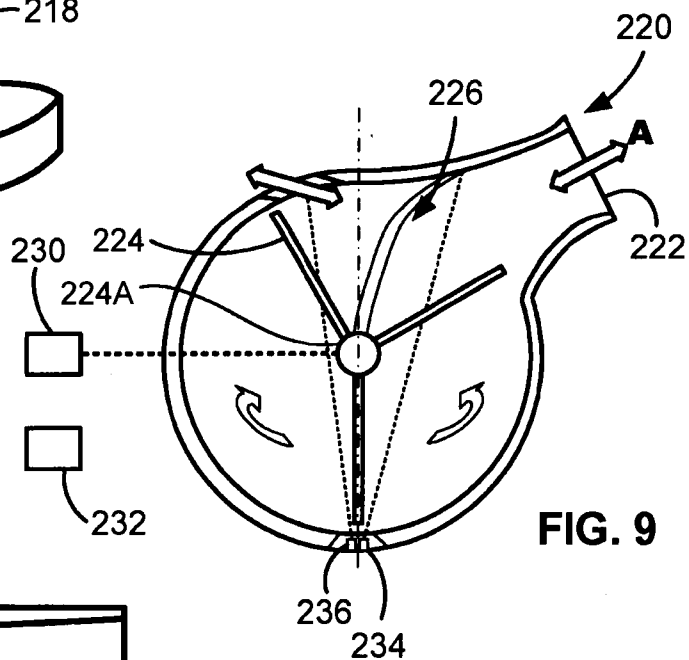
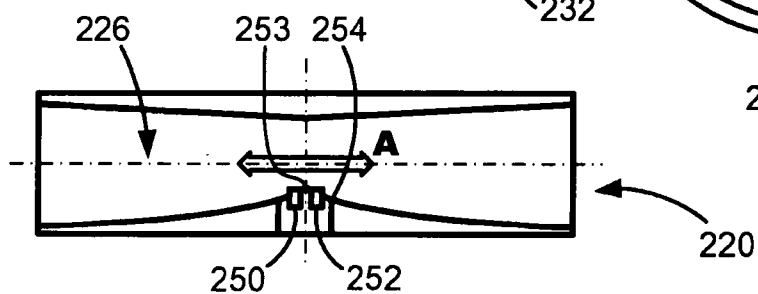


FIG. 10



MCDM – Mobile Communication & Display Module

STM –
Sensor & Transmitter Module

108

120B

120A

Web SMS –
(e.g., text4free.net)

106

104

102

116

114

112

110

120C

DPDM – Data Processing & Distribution Module

100

