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(54) **INTERNET BASED DISEASE MONITORING SYSTEM (IDMS)**

INTERNETBASIERTES KRANKHEITSÜBERWACHUNGSSYSTEM (IDMS)

SYSTÈME DE SURVEILLANCE DE MALADIE BASÉ SUR INTERNET (IDMS)

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(56) References cited:
WO-A2-2009/052828
GB-A- 2 295 650
US-A- 5 906 203
US-A1- 2008 269 673
US-A1- 2011 022 025
US-A1- 2012 029 376
US-A1- 2013 053 657
US-B1- 6 730 927

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EP 2 967 355 B1

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Description

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.

[0005] US-2012/029376-A1 is considered the closest prior art and discloses a portable hand-held spirometer for use in taking respiratory tests and storing and displaying test results. The configuration of the spirometer includes handgrips that are positioned to ensure that the user is properly positioned to provide maximum breathing required for valid test results to be obtained. The spirometer also includes a progressively illuminated indicator that can be viewed by the user during a test to provide an indication in real-time to the user of the expected/desired duration of the exhalation or inhalation test. The indicator is completely illuminated only when the measured accumulated volume of air passing through the spirometer equals a predicted volume determined based on the age, gender, height, weight and ethnicity of the user stored in the spirometer. The structures and arrangement of a turbine assembly and sensors is also disclosed. Further, a method of receiving, storing and displaying information on the spirometer via a color touch screen display is also disclosed.

[0006] GB-2295650-A discloses a peak flow meter for measuring lung function in which a deflector device is provided with oblique apertures adapted to alter the direction of air-flow from a first direction to a second direction perpendicular or at least towards the planar surface of blade means whereby the air-flow provides a force which causes said blade means to move. The blade means are blades of a turbine, the speed of rotation of which can be determined by use of optical transducer equipment.

SUMMARY

[0007] According to the present invention there is provided a device for determining body function parameters based upon the movement of a patient's breath, the device comprising: a housing forming a flow chamber having a first port configured to accept a human breath and a second port configured to exhaust human breath, the flow chamber having an interior surface; a sensing element movably mounted within the flow chamber, the sensing element being configured to move bidirectionally in response to pressure from the breath received into the first port; a biasing element configured to resist movement of the sensing element and to return the sensing element to a home position in the absence of any pres-

sure from breath received into the first port; a light source configured to transmit a light beam; a light receiver configured to receive reflected light; a transducer configured to couple to the light receiver and to convert the reflected light into electrical signals; first and second optical light pipes integrated with the sensing element and configured to transmit the light beam onto the interior surface of the flow chamber; and a processor configured to receive and process the electrical signals, the processor being configured to determine: in response to pressure from an accepted human breath, the extent of movement of the sensing element; and in response to determining the extent of the movement, the magnitude of the pressure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] 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.

FIG. 1 is a diagrammatic illustration of one embodiment of a telemedicine system with various software modules embodying the invention.
FIG. 2 is a diagrammatic illustration representing the operation of a telemedicine system illustrated in FIG. 1.
FIG. 3 is a diagrammatical illustration of a sensor and transmitter module ("STM") for use by a patient.
FIG. 4 is a flow chart illustrating the operation of the telemedicine system illustrated in FIG. 1.
FIG. 5 is a flow chart of an APP for enabling a mobile communication device to communicate with an STM.
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.
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.
FIG. 7B is a view of the modified STM shown in FIG. 7A with the sensor and transmission modules in a detached state.
FIG. 8A is a diagrammatic illustration showing another modified STM without an optical light pipe.
FIG. 8B is a view of the modified STM shown in FIG. 8A with the sensor and transmission modules in a detached state.
FIG. 8C is a diagrammatic perspective view of the modified STM shown in FIGs. 8A and 8B
FIG. 9 is a sectional view illustration of an STM utilizing a movable vane and an acoustic sensing system.
FIG. 10 is a sectional view illustration of a modified STM utilizing an acoustic sensing system without any moving parts.

[0009] 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.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0010] 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.

[0011] 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).

[0012] 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.

[0013] 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 sys-

tem 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.

[0014] 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.

[0015] 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.

[0016] 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.

[0017] 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.

[0018] 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.

[0019] 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 websys for multiple sensor systems) and PC software module for insurance companies 112, clinics and medical facilities 114, pharmacies 116, etc.

[0020] 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.

[0021] 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.

[0022] 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.

[0023] 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.

[0024] 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.

[0025] 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.

[0026] 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.

[0027] 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.

[0028] 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.

[0029] 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.

[0030] 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.

[0031] 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.

[0032] 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.

[0033] 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.

[0034] 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.

[0035] 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.

[0036] 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.

[0037] 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.

[0038] 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.

[0039] 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.

[0040] 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.

[0041] 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.

[0042] 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.

[0043] 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.

[0044] 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.

[0045] 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.

[0046] 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.

[0047] 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.

[0048] 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 reflected light back to the device 216. In FIG. 7A, the device 261 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.

[0049] 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.

[0050] 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.

[0051] 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 results 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.

[0052] 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 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.

[0053] 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.

[0054] 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.

[0055] 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.

[0056] 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.

[0057] 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.

[0058] 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.

Claims

1. A device (200) for determining body function parameters based upon the movement of a patient's breath, the device comprising:

   a housing forming a flow chamber (202) having a first port (222) configured to accept a human breath and a second port configured to exhaust human breath, the flow chamber (202) having an interior surface;
   a sensing element (206) movably mounted within the flow chamber (202), the sensing element (206) being configured to move bidirectionally in response to pressure from the breath received into the first port (222);
   a biasing element configured to resist movement of the sensing element (206) and to return the sensing element (206) to a home position in the absence of any pressure from breath received into the first port (222);
   a light source (208) configured to transmit a light beam;
   a light receiver (212) configured to receive reflected light;
   a transducer configured to couple to the light receiver and to convert the reflected light into electrical signals;
   first and second optical light pipes (210, 214) integrated with the sensing element (206) and configured to transmit the light beam onto the interior surface of the flow chamber (202); and
   a processor (232) configured to receive and process the electrical signals, the processor (232) being configured to determine:

      in response to pressure from an accepted human breath, the extent of movement of the sensing element (206); and
      in response to determining the extent of the movement, the magnitude of the pressure.

2. The device (200) of claim 1, wherein the light beam is conveyed to the sensing element (206) to sense its movement and transmitted onto the interior sur-

face of the flow chamber (202) as the sensing element (206) is moved within the flow chamber (202).

3. The device (200) of claim 1, wherein the housing forming the flow chamber (202) is detachable from a base (204).

4. The device (200) of claim 3, further comprising a fluid barrier configured to prevent bacterial cross-contamination between the housing and the base (204).

5. The device (200) of claim 1, wherein the sensing element is a vane (206) adapted for pivotal movement and the biasing element is a spring allowing bidirectional movement from a central position.

6. The device (200) of claim 1, wherein the light source (208) is selected from a group consisting of a light emitting diode and a laser diode.

7. The device (200) of claim 1, wherein the device (200) further comprises a transmitter coupled to the processor (232) and configured to produce output signals corresponding to the extent of the movement of the sensing element (206) and the speed of displacement against the magnitude of pressure from the human breath.

8. The device (200) of claim 7, wherein the output signals from the device (200) include information identifying the device for linking the device (200) to server-based data associated with a patient to which the device is prescribed.

9. The device (200) of claim 7, wherein the transmitter in the device (200) is configured to broadcast the output signals as broadcast signals in a near-field frequency band such that a mobile communication device (106) can detect and receive the broadcast signals.

10. The device (200) of claim 9, wherein the output signals from the device (200) are encrypted.

Patentansprüche

1. Vorrichtung (200) zum Bestimmen von Körperfunktionsparametern basierend auf der Bewegung des Atems eines Patienten, wobei die Vorrichtung Folgendes umfasst:

ein Gehäuse, das eine Strömungskammer (202) bildet, die einen ersten Anschluss (222), der dazu konfiguriert ist, einen menschlichen Atem aufzunehmen, und einen zweiten Anschluss, der dazu konfiguriert ist, einen menschlichen Atem auszustoßen, aufweist, wobei die Strömungskammer (202) eine Innenfläche aufweist;
ein Erfassungselement (206), das beweglich innerhalb der Strömungskammer (202) befestigt ist, wobei das Erfassungselement (206) dazu konfiguriert ist, sich als Reaktion auf einen Druck von dem Atem, der in dem ersten Anschluss (222) aufgenommen wird, in zwei Richtungen zu bewegen;
ein Vorspannelement, das dazu konfiguriert ist, einer Bewegung des Erfassungselements (206) zu widerstehen und das Erfassungselement (206) in Abwesenheit von jeglichem Druck von einem Atem, der in dem ersten Anschluss (222) aufgenommen wird, in eine Ausgangsposition zurückzubringen;
eine Lichtquelle (208), die dazu konfiguriert ist, einen Lichtstrahl zu übertragen;
einen Lichtempfänger (212), der dazu konfiguriert ist, ein reflektiertes Licht zu empfangen;
einen Wandler, der dazu konfiguriert ist, sich an den Lichtempfänger zu koppeln und das reflektierte Licht in elektrische Signale umzuwandeln;
eine erste und eine zweite optische Lichtleitung (210, 214), die in dem Erfassungselement (206) integriert sind und dazu konfiguriert sind, den Lichtstrahl auf die Innenfläche der Strömungskammer (202) zu übertragen; und
einen Prozessor (232), der dazu konfiguriert ist, die elektrischen Signale zu empfangen und zu verarbeiten, wobei der Prozessor (232) dazu konfiguriert ist, Folgendes zu bestimmen:

als Reaktion auf einen Druck von einem aufgenommenen menschlichen Atem, das Ausmaß der Bewegung des Erfassungselements (206); und
als Reaktion auf das Bestimmen des Ausmaßes der Bewegung, die Größe des Drucks.

2. Vorrichtung (200) nach Anspruch 1, wobei der Lichtstrahl an das Erfassungselement (206) übermittelt wird, um dessen Bewegung zu erfassen, und auf die Innenfläche der Strömungskammer (202) übertragen wird, während das Erfassungselement (206) innerhalb der Strömungskammer (202) bewegt wird.

3. Vorrichtung (200) nach Anspruch 1, wobei das Gehäuse, das die Strömungskammer (202) bildet, von einer Basis (204) gelöst werden kann.

4. Vorrichtung (200) nach Anspruch 3, ferner umfassend eine Fluidbarriere, die dazu konfiguriert ist, eine bakterielle Kreuzkontamination zwischen dem Gehäuse und der Basis (204) zu verhindern.

5. Vorrichtung (200) nach Anspruch 1, wobei das Erfassungselement eine Schaufel (206) ist, die für eine

Schwenkbewegung angepasst ist, und das Vorspannelement eine Feder ist, die eine Bewegung von einer mittigen Position in zwei Richtungen ermöglicht.

6. Vorrichtung (200) nach Anspruch 1, wobei die Lichtquelle (208) ausgewählt ist aus einer Gruppe bestehend aus einer lichtemittierenden Diode und einer Laserdiode.

7. Vorrichtung (200) nach Anspruch 1, wobei die Vorrichtung (200) ferner einen Sender umfasst, der an den Prozessor (232) gekoppelt ist und dazu konfiguriert ist, Ausgabesignale zu produzieren, die dem Ausmaß der Bewegung des Erfassungselements (206) und der Geschwindigkeit einer Verschiebung gegenüber der Größe des Drucks von dem menschlichen Atem entsprechen.

8. Vorrichtung (200) nach Anspruch 7, wobei die Ausgabesignale von der Vorrichtung (200) Informationen einschließen, die die Vorrichtung identifizieren, um die Vorrichtung (200) mit serverbasierten Daten zu verknüpfen, die mit einem Patienten assoziiert sind, dem die Vorrichtung verschrieben wurde.

9. Vorrichtung (200) nach Anspruch 7, wobei der Sender in der Vorrichtung (200) dazu konfiguriert ist, die Ausgabesignale als Rundrufsignale über Rundruf in einem Nahfeld-Frequenzbereich zu senden, sodass eine mobile Kommunikationsvorrichtung (106) die Rundrufsignale detektieren und empfangen kann.

10. Vorrichtung (200) nach Anspruch 9, wobei die Ausgabesignale von der Vorrichtung (200) verschlüsselt sind.

Revendications

1. Dispositif (200) pour la détermination de paramètres de fonctions corporelles en fonction du mouvement de la respiration d'un patient, le dispositif comprenant :

un boîtier formant une chambre d'écoulement (202) possédant un premier orifice (222), configuré pour recevoir un souffle humain, et un deuxième orifice, configuré pour évacuer un souffle humain, la chambre d'écoulement (202) possédant une surface interne ;
un élément détecteur (206) monté de façon amovible au sein de la chambre d'écoulement (202), l'élément détecteur (206) étant configuré pour effectuer un déplacement bidirectionnel sous l'effet de la pression exercée par le souffle reçu dans le premier orifice (222) ;
un élément de sollicitation configuré pour résister au mouvement de l'élément détecteur (206) et replacer l'élément détecteur (206) dans une position de départ en l'absence de toute pression de souffle reçue dans le premier orifice (222) ;
une source lumineuse (208) configurée pour transmettre un faisceau lumineux ;
un récepteur de lumière (212) configuré pour recevoir de la lumière réfléchie ;
un transducteur configuré pour se coupler au récepteur de lumière, et convertir la lumière réfléchie en signaux électriques ;
des premier et deuxième conducteurs de lumière optiques (210, 214) intégrés avec l'élément détecteur (206), et configurés pour transmettre le faisceau lumineux sur la surface intérieure de la chambre d'écoulement (202) ; et and
un processeur (232) configuré pour recevoir et traiter les signaux électriques, le processeur (232) étant configuré pour déterminer :

en réponse à la pression exercée par un souffle humain admis, l'ampleur du mouvement de l'élément détecteur (206) ; et
en réponse à la détermination de l'ampleur du mouvement, la magnitude de la pression.

2. Dispositif (200) selon la revendication 1, le faisceau lumineux étant dirigé vers l'élément détecteur (206) pour détecter son mouvement et transmis sur la surface intérieure de la chambre d'écoulement (202) lors du déplacement de l'élément détecteur (206) au sein de la chambre d'écoulement (202).

3. Dispositif (200) selon la revendication 1, le boîtier formant la chambre d'écoulement (202) pouvant être détaché d'un socle (204).

4. Dispositif (200) selon la revendication 3, comprenant en outre une barrière fluidique configurée pour empêcher toute contamination bactérienne croisée entre le boîtier et le socle (204).

5. Dispositif (200) selon la revendication 1, l'élément détecteur étant une pale (206) adaptée pour effectuer un mouvement pivotant, et l'élément de sollicitation étant un ressort permettant un mouvement bidirectionnel depuis une position centrale.

6. Dispositif (200) selon la revendication 1, la source lumineuse (208) étant sélectionnée parmi un groupe composé d'une diode électroluminescente et d'une diode laser.

7. Dispositif (200) selon la revendication 1, le dispositif (200) comprenant en outre un transmetteur couplé au processeur (232) et configuré pour émettre des

signaux de sortie correspondant à l'ampleur du mouvement de l'élément détecteur (206) et à la vitesse de déplacement contre la magnitude de la pression du souffle humain.

8. Dispositif (200) selon la revendication 7, les signaux de sortie provenant du dispositif (200) comprenant des informations identifiant le dispositif pour relier le dispositif (200) aux données basées sur serveur associées avec un patient auquel le dispositif a été prescrit.

9. Dispositif (200) selon la revendication 7, le transmetteur dans le dispositif (200) étant configuré pour diffuser les signaux de sortie en tant que signaux diffusés dans une fréquence en champ proche, afin qu'un dispositif de communication mobile (106) puisse détecter et recevoir les signaux diffusés.

10. Dispositif (200) selon la revendication 9, les signaux de sortie provenant du dispositif (200) étant cryptés.

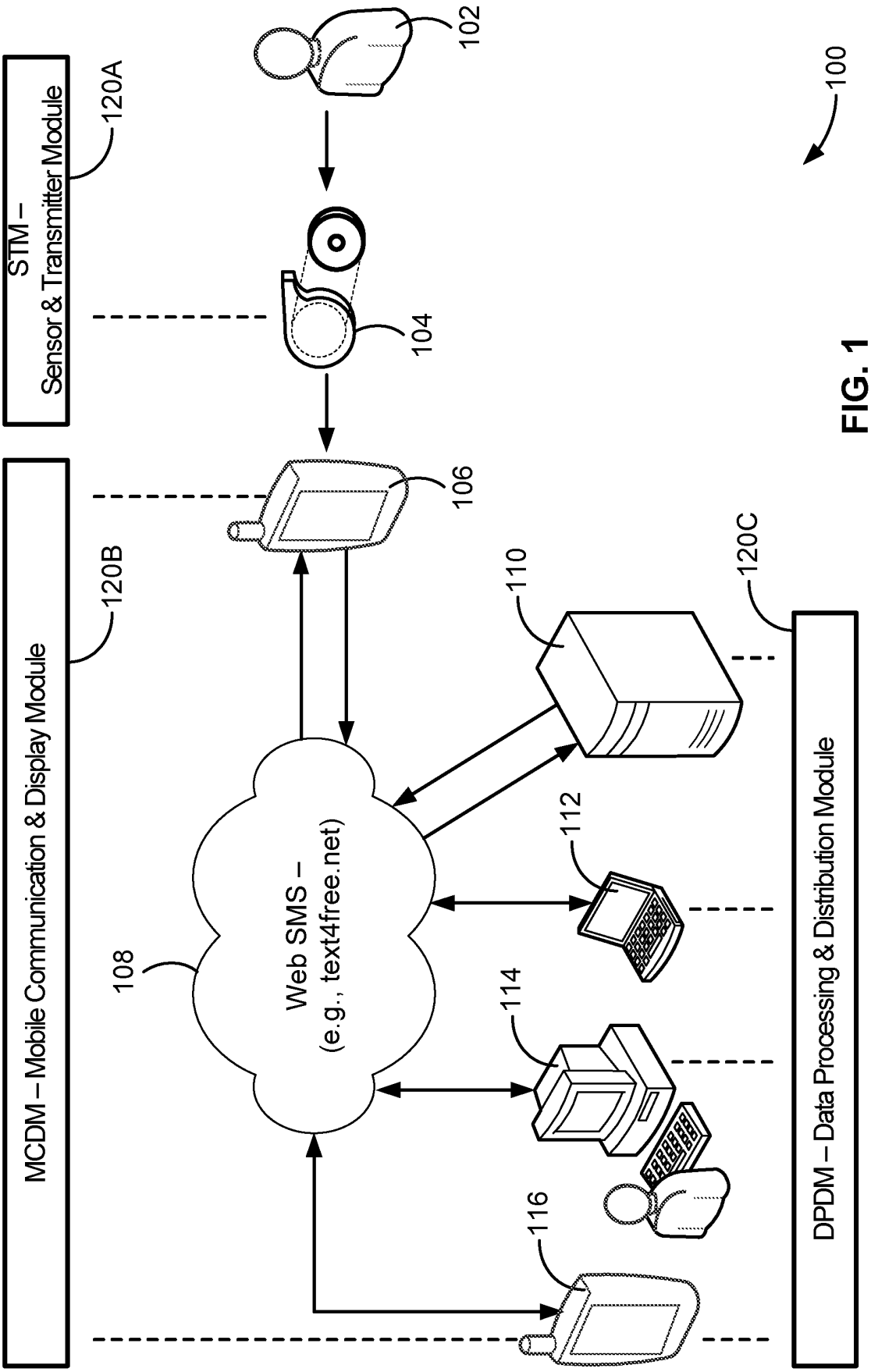

STM –
Sensor & Transmitter Module
120A
102
104
106
MCDM – Mobile Communication & Display Module
120B
108
Web SMS –
(e.g., text4free.net)
110
120C
112
114
116
DPDM – Data Processing & Distribution Module
100

FIG. 1

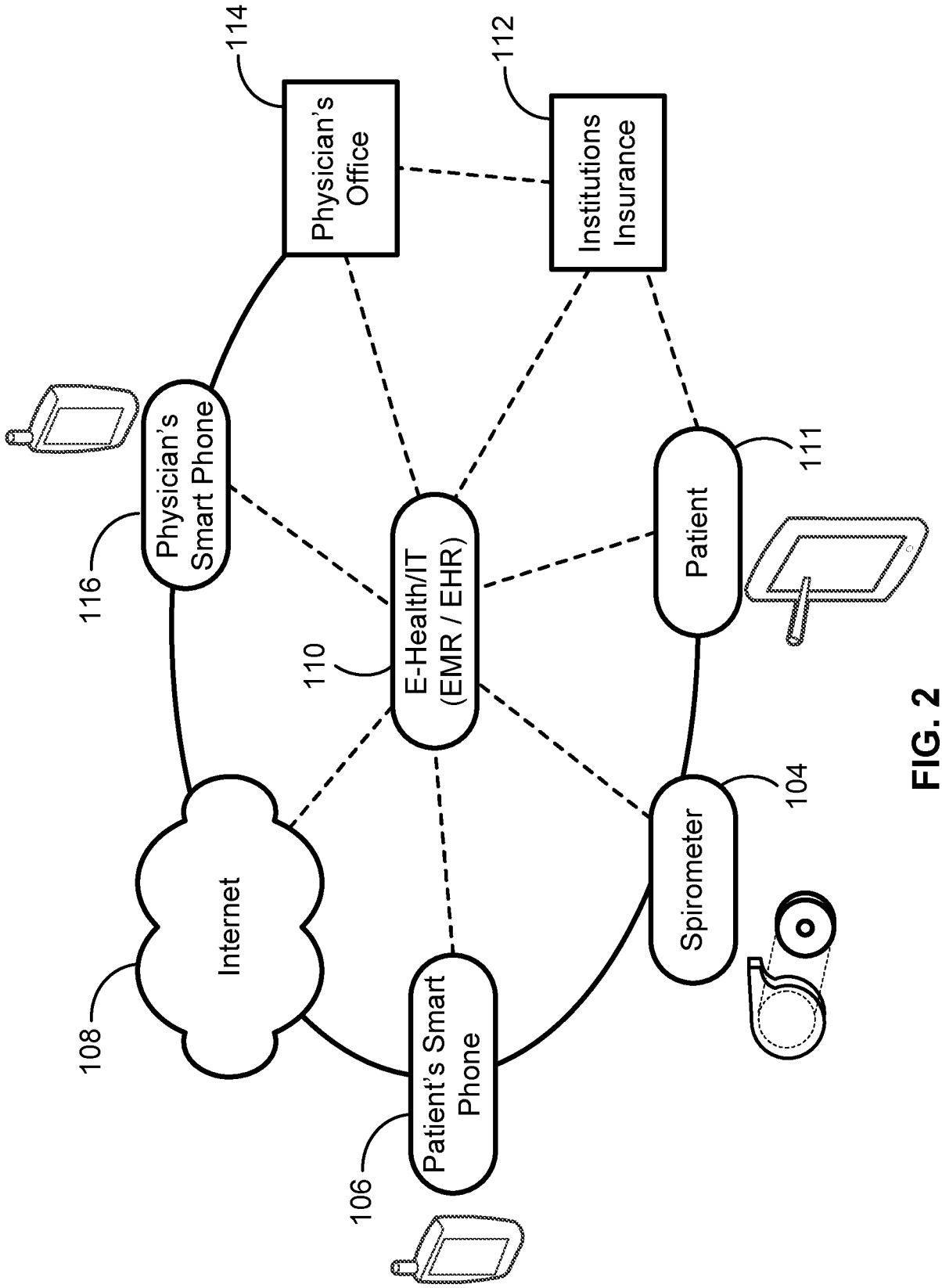

114
Physician's Office
112
Institutions Insurance
Physician's Smart Phone
116
E-Health/IT (EMR / EHR)
110
Patient
111
Internet
108
Spirometer
104
Patient's Smart Phone
106

FIG. 2

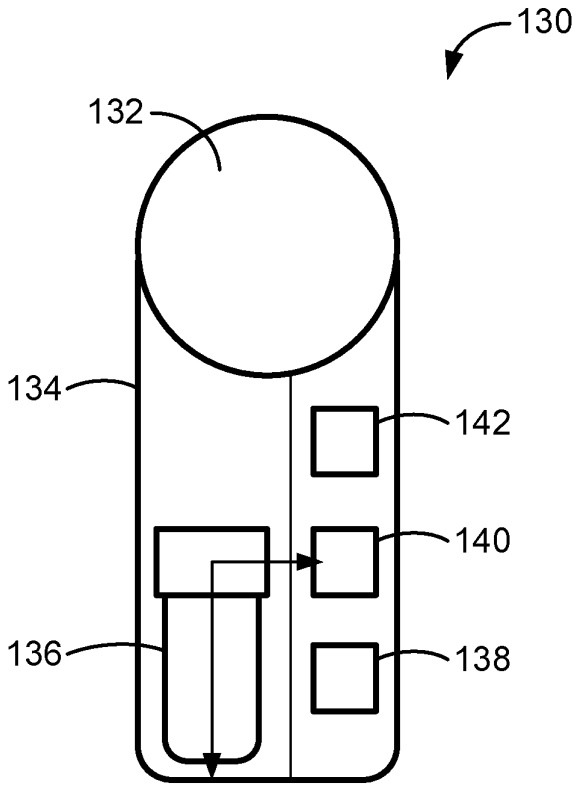


FIG. 3

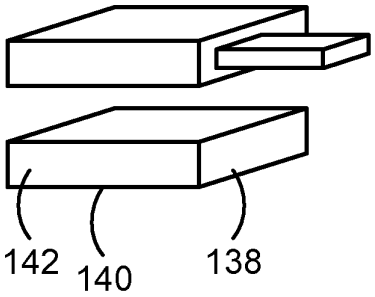


FIG. 3A

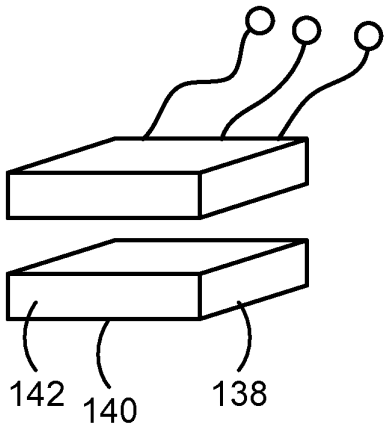


FIG. 3B

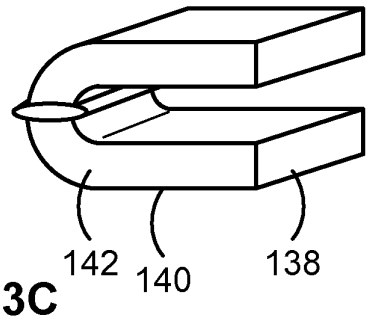


FIG. 3C

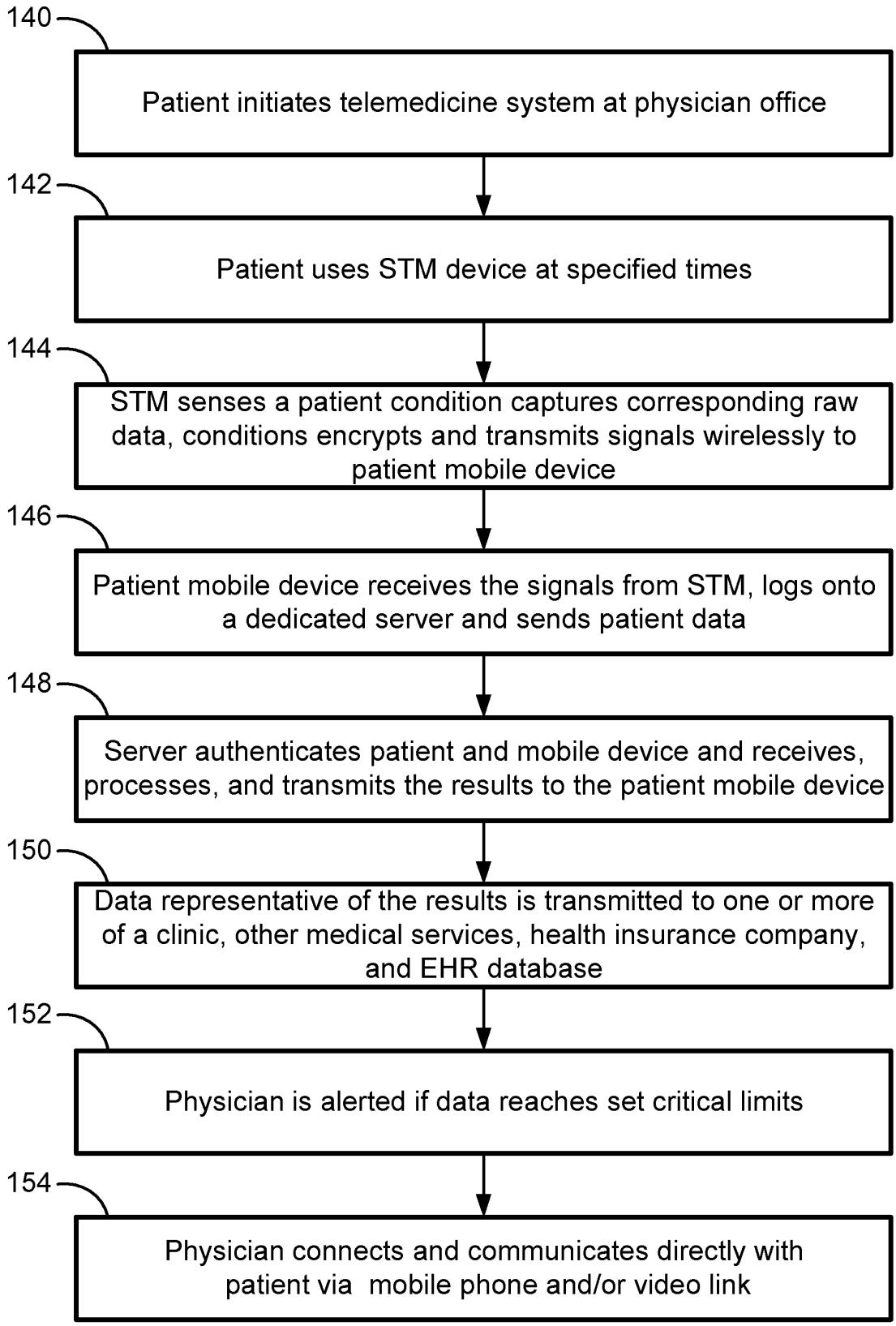

140
Patient initiates telemedicine system at physician office
142
Patient uses STM device at specified times
144
STM senses a patient condition captures corresponding raw data, conditions encrypts and transmits signals wirelessly to patient mobile device
146
Patient mobile device receives the signals from STM, logs onto a dedicated server and sends patient data
148
Server authenticates patient and mobile device and receives, processes, and transmits the results to the patient mobile device
150
Data representative of the results is transmitted to one or more of a clinic, other medical services, health insurance company, and EHR database
152
Physician is alerted if data reaches set critical limits
154
Physician connects and communicates directly with patient via mobile phone and/or video link

FIG. 4

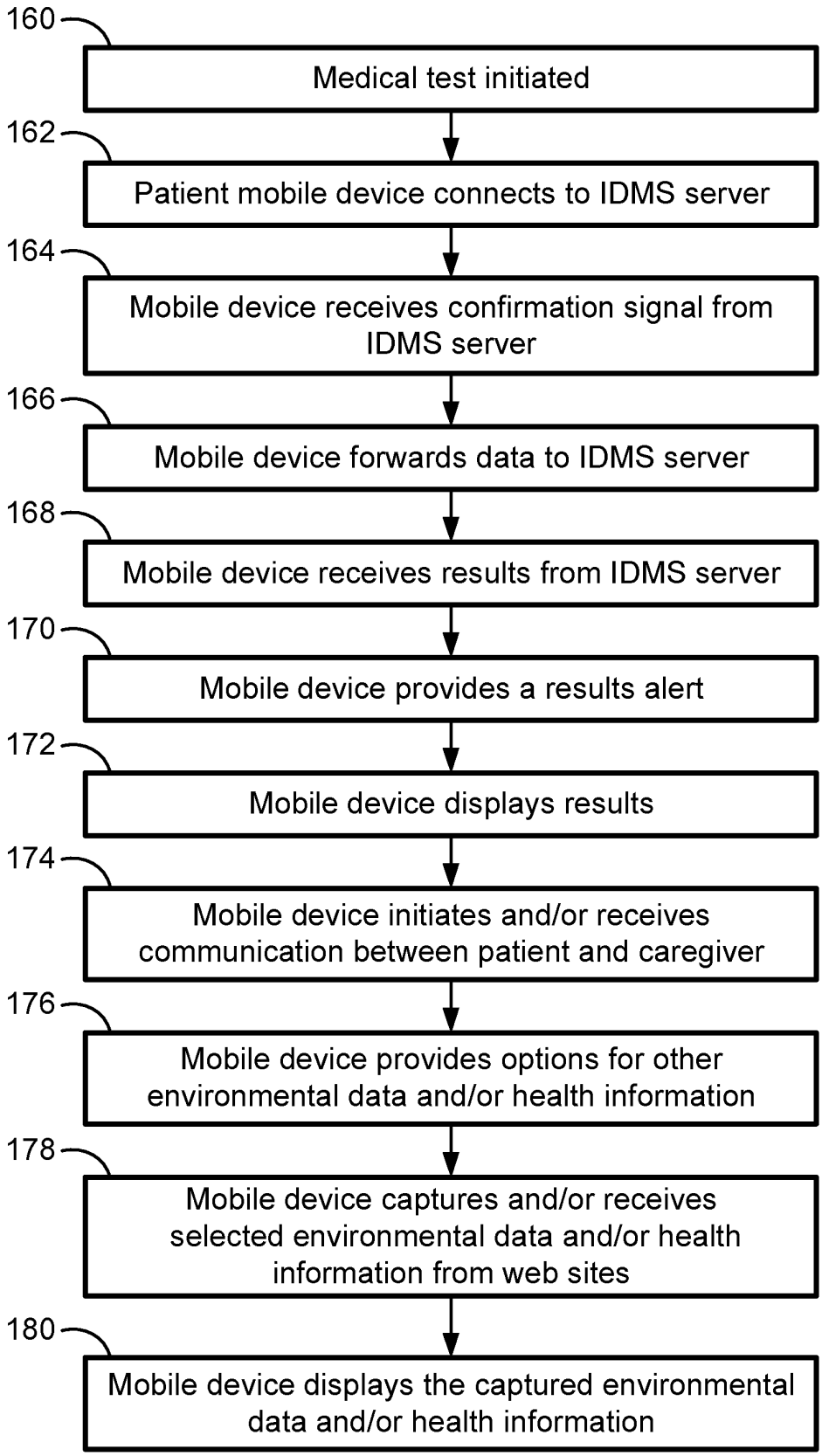

160
Medical test initiated
162
Patient mobile device connects to IDMS server
164
Mobile device receives confirmation signal from IDMS server
166
Mobile device forwards data to IDMS server
168
Mobile device receives results from IDMS server
170
Mobile device provides a results alert
172
Mobile device displays results
174
Mobile device initiates and/or receives communication between patient and caregiver
176
Mobile device provides options for other environmental data and/or health information
178
Mobile device captures and/or receives selected environmental data and/or health information from web sites
180
Mobile device displays the captured environmental data and/or health information

FIG. 5

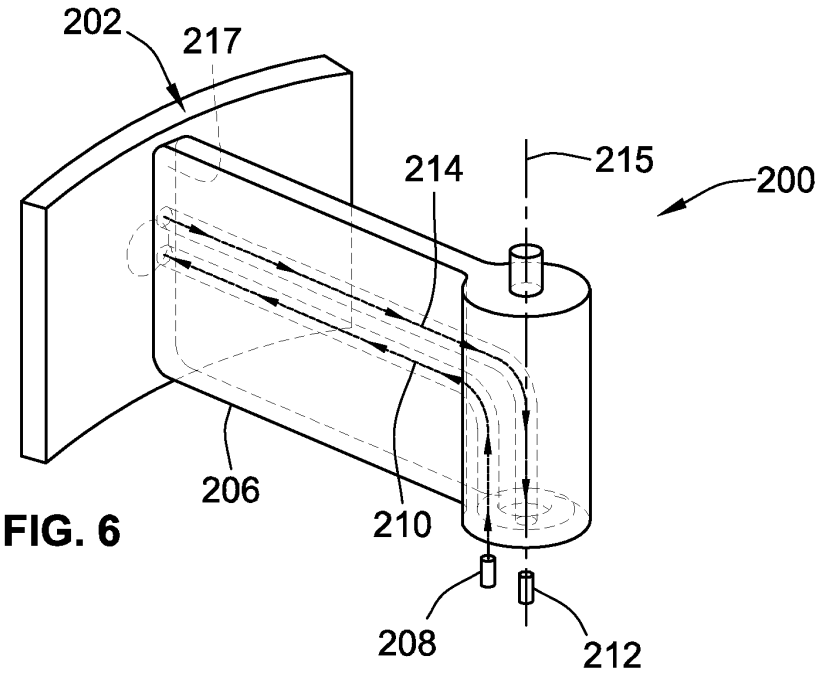


FIG. 6

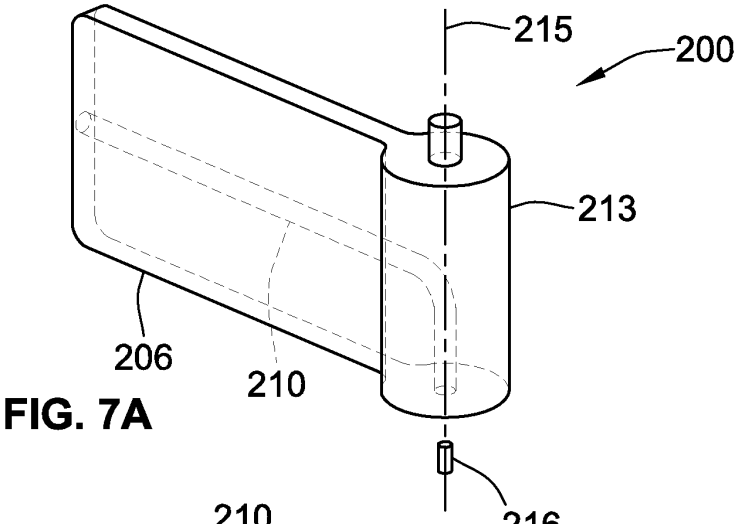


FIG. 7A

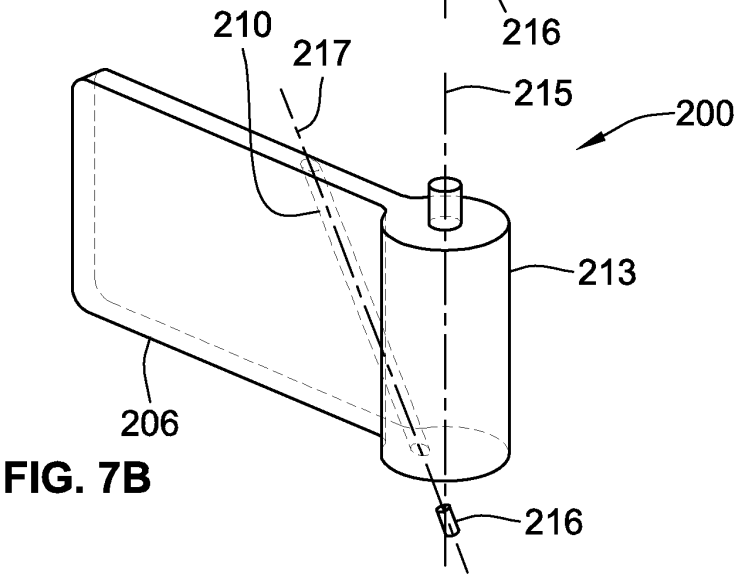


FIG. 7B

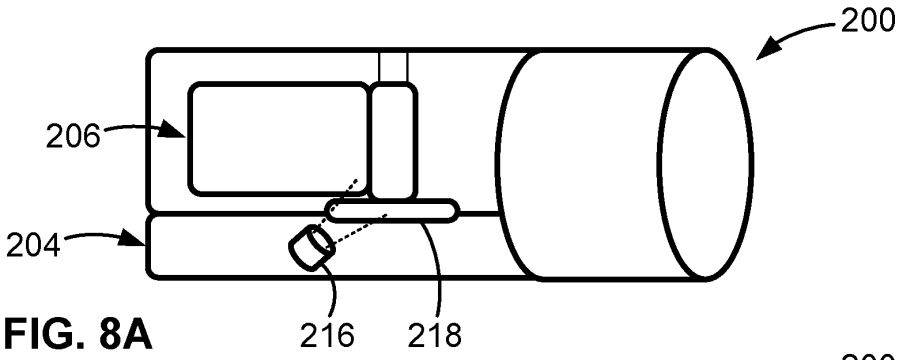


FIG. 8A

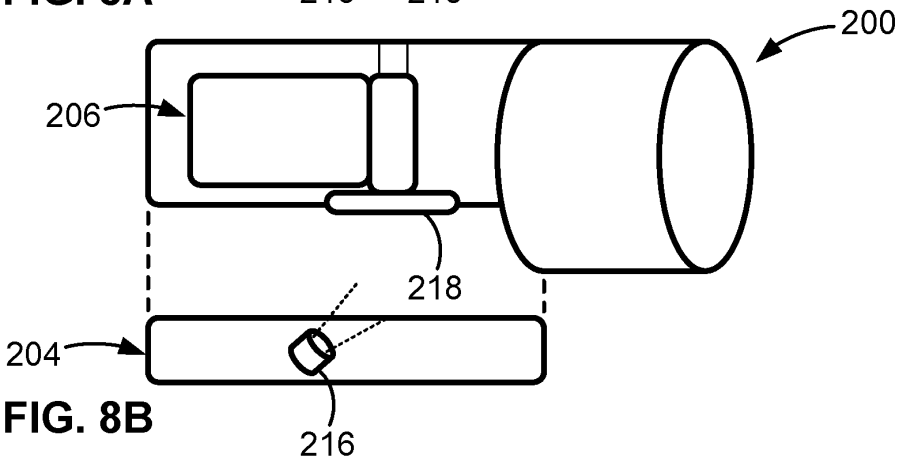


FIG. 8B

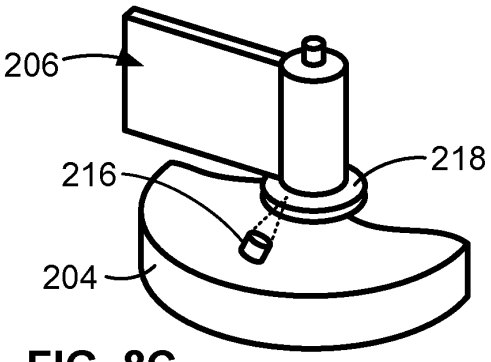


FIG. 8C

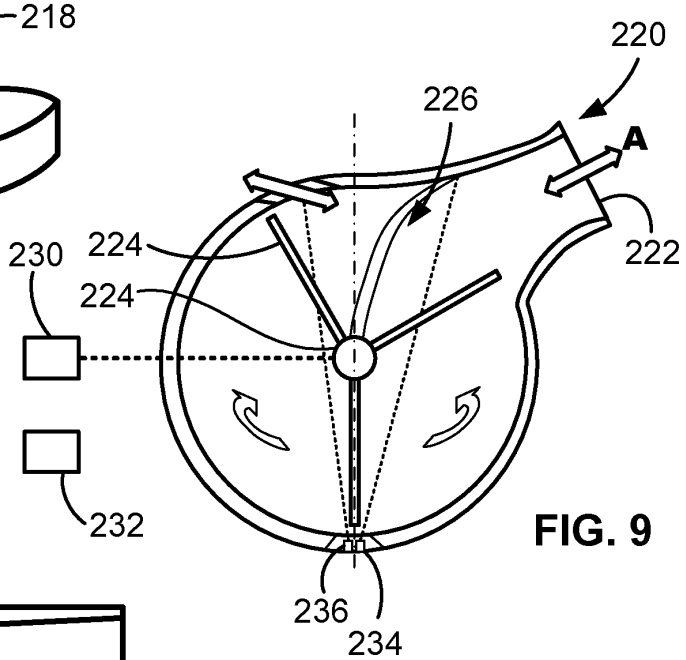
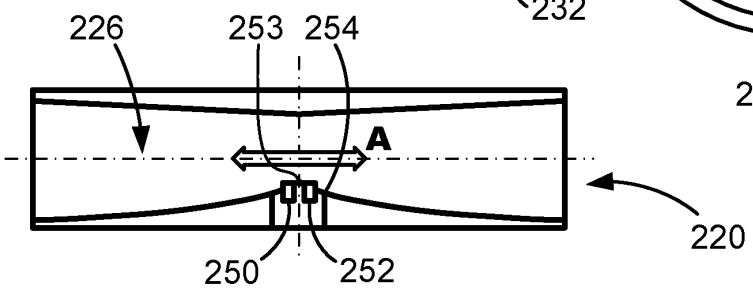


FIG. 9

FIG. 10



REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 2012029376 A1 **[0005]**
- GB 2295650 A **[0006]**
- US 5816246 A **[0017]**

专利名称(译)	基于互联网的疾病监测系统（IDMS）		
公开(公告)号	EP2967355A4	公开(公告)日	2016-10-26
申请号	EP2014774248	申请日	2014-03-13
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申请(专利权)人(译)	MIRZA，M.，祖拜尔		
当前申请(专利权)人(译)	MIRZA，M.，祖拜尔		
[标]发明人	MIRZA M ZUBAIR		
发明人	MIRZA, M., ZUBAIR		
IPC分类号	A61B5/00 A61B5/09		
CPC分类号	A61B5/0022 A61B5/0873 A61B5/09 A61B5/6898 A61B2560/0443 A61B2562/0204 A61B2562/0247 G06F19/3418 G06F19/3456 G06Q30/04 G16H40/60 G16H40/63 G16H50/20 H04N21/8547 A61B5/08		
优先权	61/785696 2013-03-14 US		
其他公开文献	EP2967355B1 EP2967355A2		
外部链接	Espacenet		

摘要(译)

基于互联网的疾病监测系统，包括患者操作设备，移动通信设备和远程服务器。 病人操作的设备包括响应于病人状况产生输入信号的传感器，以及耦合到传感器的传感器传输模块。 该传感器传输模块包括可操作地耦合到至少一个处理器的数字信号处理器，该数字信号处理器被配置为从传感器接收输入信号并将该输入信号转换为数字数据。 所述至少一个处理器可操作地耦合到发射器，所述至少一个处理器被配置用于将所述数字数据转换成数据包，所述数据包包括与耦合到所述传感器的医疗设备相关联的设备标识符； 所述发送器被配置为加密所述数字数据，并通过SMS将所述数据包发送至移动通信设备，以进一步发送至远程服务器，以至少部分地基于所述设备标识符来对所述数字数据进行解密和分析。 移动通信设备响应于从发射机接收到数据包，移动通信设备将数据包转发到预定的网络地址。 远程服务器位于网络地址处，并且响应于从移动通信设备接收到的数据包，远程服务器分析该数据包并产生表示分析结果的分析信号，并将分析信号发送到与该数据包相关联的预定接收者。 病人操作设备。