A monitoring device, method and system for monitoring vital signs of a patient over a wireless network are disclosed herein. The monitoring device includes an adhesive patch sensor, typically mounted on a patient’s head, and a processing component. The adhesive patch sensor typically includes an optical system that generates an optical waveform, and an electrode that generates an electrical waveform. The processing component processes the optical and electrical waveforms, along with a calibration table, to determine the patient’s vital signs.
PATCH SENSOR FOR MEASURING BLOOD PRESSURE WITHOUT A CUFF


STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not Applicable

BACKGROUND OF THE INVENTION

[0003] 1. Field of the Invention

[0004] The present invention relates to a device, method and system for measuring vital signs, particularly blood pressure.

[0005] 2. Description of Related Art

[0006] Pulse oximeters are medical devices featuring an optical module, typically worn on a patient's finger or ear lobe, and a processing module that analyzes data generated by the optical module. The optical module typically includes first and second light sources (e.g., light-emitting diodes, or LEDs) that transmit optical radiation at, respectively, red (X 630-670 nm) and infrared (λ=800-1200 nm) wavelengths. The optical module also features a photodetector that detects radiation transmitted or reflected by an underlying artery. Typically the red and infrared LEDs sequentially emit radiation that is partially absorbed by blood flowing in the artery. The photodetector is synchronized with the LEDs to detect transmitted or reflected radiation. In response, the photodetector generates a separate radiation-induced signal for each wavelength. The signal, called a plethysmograph, varies in a time-dependent manner as each heartbeat varies the volume of arterial blood and hence the amount of transmitted or reflected radiation. A microprocessor in the pulse oximeter processes the relative absorption of red and infrared radiation to determine the oxygen saturation in the patient's blood. A number between 94%-100% is considered normal, while a value below 85% typically indicates the patient requires hospitalization. In addition, the microprocessor analyzes time-dependent features in the plethysmograph to determine the patient's heart rate.

[0007] Pulse oximeters work best when the appendage they attach to (e.g., a finger) is at rest. If the finger is moving, for example, the light source and photodetector within the optical module typically move relative to the underlying artery. This generates 'noise' in the plethysmograph, which in turn can lead to motion-related artifacts in data describing pulse oximetry and heart rate. Ultimately this reduces the accuracy of the measurement. Another medical device, called a sphygmomanometer, measures a patient's blood pressure using an inflatable cuff and a sensor (e.g., a stethoscope) that detects blood flow by listening for sounds called the Korotkoff sounds. During a measurement, a medical professional typically places the cuff around the patient's arm and inflates it to a pressure that exceeds the systolic blood pressure. The medical professional then incrementally reduces pressure in the cuff while listening for flowing blood with the stethoscope. The pressure value at which blood first begins to flow past the deflating cuff, indicated by a Korotkoff sound, is the systolic pressure. The stethoscope monitors this pressure by detecting strong, periodic acoustic ‘beats’ or ‘taps’ indicating that the blood is flowing past the cuff (i.e., the systolic pressure barely exceeds the cuff pressure). The minimum pressure in the cuff that restricts blood flow, as detected by the stethoscope, is the diastolic pressure. The stethoscope monitors this pressure by detecting another Korotkoff sound, in this case a 'leveling off' or disappearance in the acoustic magnitude of the periodic beats, indicating that the cuff no longer restricts blood flow (i.e., the diastolic pressure barely exceeds the cuff pressure).

[0008] Low-cost, automated devices measure blood pressure using an inflatable cuff and an automated acoustic or pressure sensor that measures blood flow. These devices typically feature cuffs fitted to measure blood pressure in a patient's wrist, arm or finger. During a measurement, the cuff automatically inflates and then incrementally deflates while the automated sensor monitors blood flow. A microcontroller in the automated device then calculates blood pressure. Cuff-based blood-pressure measurements such as these typically only determine the systolic and diastolic blood pressures; they do not measure dynamic, time-dependent blood pressure.

[0009] Data indicating blood pressure are most accurately measured during a patient’s appointment with a medical professional, such as a doctor or a nurse. Once measured, the medical professional can manually record these data in either a written or electronic file. Appointments typically take place a few times each year. Unfortunately, in some cases, patients experience ‘white coat syndrome’ where anxiety during the appointment affects the blood pressure that is measured. For example, white coat syndrome can elevate a patient’s heart rate and blood pressure; this, in turn, can lead to an inaccurate diagnoses.

[0010] Various methods have been disclosed for using pulse oximeters to obtain arterial blood pressure. One such method is disclosed in U.S. Pat. No. 5,140,990 to Jones et al., for a ‘Method Of Measuring Blood Pressure With A Photoplethysmograph’. The '990 Patent discloses using a pulse oximeter with a calibrated auxiliary blood pressure to generate a constant that is specific to a patient’s blood pressure. Another method for using a pulse oximeter to measure blood pressure is disclosed in U.S. Pat. No. 6,616,613 to Goodman for a ‘Physiological Signal Monitoring System’. The '613 Patent discloses processing a pulse oximetry signal in combination with information from a calibrating device to determine a patient's blood pressure.

[0011] Chen et al., U.S. Pat. No. 6,599,251, discloses a system and method for monitoring blood pressure by detecting pulse signals at two different locations on a subject's body, preferably on the subject's finger and earlobe. The pulse signals are preferably detected using pulse oximetry devices, and then processed to determine blood pressure.

[0012] Schulze et al., U.S. Pat. No. 6,556,852, discloses an earpiece having an embedded pulse oximetry device and thermopile to monitor and measure physiological variables of a user.

[0013] Jobsis et al., U.S. Pat. No. 4,380,240, discloses an optical probe featuring a light source and a light detector incorporated into channels within a deformable mounting structure which is adhered to a strap. The light source and the light detector are secured to the patient’s body by
adhesive tapes and pressure induced by closing the strap around a portion of the body.

[0014] Tan et al., U.S. Pat. No. 4,825,879, discloses an optical probe with a T-shaped wrap having a vertical stem and a horizontal cross bar, which is utilized to secure a light source and an optical sensor in optical contact with a finger. A metallic material is utilized to reflect heat back to the patient’s body and to provide opacity to interfering ambient light. The sensor is secured to the patient’s body using an adhesive or hook-and-loop material.

[0015] Modgil et al., U.S. Pat. No. 6,681,454, discloses a strap composed of an elastic material that wraps around the outside of a pulse oximeter probe and is secured to the oximeter probe by attachment mechanisms such as Velcro.

[0016] Diab et al., U.S. Pat. Nos. 6,813,511 and 6,678,543 discloses a disposable optical probe that reduces noise during a measurement. The probe is adhesively secured to a patient’s finger, toe, forehead, earlobe or lip, and can include reusable and disposable portions.

BRIEF SUMMARY OF THE INVENTION

[0017] The present invention provides a cuffless, blood-pressure monitor, featuring an adhesive patch. The patch is disposable and is typically used for 24-72 hours. The blood pressure monitor makes a transdermal, optical measurement of the time-dependent dynamics of blood flowing in an underlying artery. A processor analyzes this information, typically with a calibration table, to determine blood pressure. Once determined, the processor sends it to a hand-held wireless component (e.g., a cellular phone or wireless PDA). The processing component preferably features an embedded, short-range wireless transceiver and a software platform that displays, analyzes, and then transmits the information through a wireless network to an Internet-based system. With this system a medical professional can continuously monitor a patient’s blood pressure during their day-to-day activities. Monitoring patients in this manner minimizes erroneous measurements due to ‘white coat syndrome’ and increases the accuracy of a blood-pressure measurement.

[0018] The invention has many advantages. In particular, one aspect of the invention provides a system that continuously monitors a patient’s blood pressure using a cuffless blood pressure monitor and an off-the-shelf mobile communication device. Information describing the blood pressure can be viewed using an Internet-based website, using a personal computer, or simply by viewing a display on the mobile device. Blood-pressure information measured continuously throughout the day provides a relatively comprehensive data set compared to that measured during isolated medical appointments. This approach identifies trends in a patient’s blood pressure, such as a gradual increase or decrease, which may indicate a medical condition that requires treatment. The invention also minimizes effects of ‘white coat syndrome’ since the monitor automatically and continuously makes measurements away from a medical office with basically no discomfort to the patient. Real-time, automatic blood pressure measurements, followed by wireless transmission of the data, are only practical with a non-invasive, cuffless monitor like that of the present invention. Measurements can be made completely unobtrusive to the patient.

[0019] The monitor can also characterize the patient’s heart rate and blood oxygen saturation using the same optical system for the blood-pressure measurement. This information can be wirelessly transmitted along with blood-pressure information and used to further diagnose the patient’s cardiac condition.

[0020] The monitor is small, easily worn by the patient during periods of exercise or day-to-day activities, and makes a non-invasive blood-pressure measurement in a matter of seconds. The resulting information has many uses for patients, medical professionals, insurance companies, pharmaceutical agencies conducting clinical trials, and organizations for home-health monitoring.

[0021] Having briefly described the present invention, the above and further objects, features and advantages thereof will be recognized by those skilled in the pertinent art from the following detailed description of the invention when taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWINGS

[0022] FIG. 1A is a schematic top view of an adhesive patch sensor that measures blood pressure according to the invention;

[0023] FIG. 1B is a schematic, cross-sectional view of the patch sensor of FIG. 1A;

[0024] FIG. 2 is a graph of time-dependent optical and electrical waveforms generated by the patch sensor of FIG. 1A;

[0025] FIG. 3 is a schematic diagram of the electrical components of a processing module connected to the patch sensor of FIG. 1A;

[0026] FIGS. 4A and 4B are schematic diagrams of the patch sensor of FIG. 1A attached to, respectively, a patient’s forehead and ear;

[0027] FIG. 5 is a schematic diagram of a head-mounted sensor similar to that shown in FIG. 4A connected to a belt-mounted processing module using a wireless link;

[0028] FIG. 6 is a schematic view of an Internet-based system used to send vital-sign information from a patient to an Internet-accessible website.

DETAILED DESCRIPTION OF THE INVENTION

[0029] FIGS. 1A and 1B show an adhesive patch sensor 20 according to the invention that features a pair of LEDs 10, 12 and photodetector 14 that, when attached to a patient, generate an optical waveform (31 in FIG. 2). A horseshoe-shaped metal electrode 17 surrounds these optical components and generates an electrical waveform (32 in FIG. 2). The electrical and optical waveforms, once generated, pass through a cable 18 to a processing module, which analyzes them as described in detail below to measure a patient’s systolic and diastolic blood pressure, heart rate, and pulse oximetry. The patch sensor 20 features an adhesive component 19 that adheres to the patient’s skin and secures the LEDs 10, 12, photodetector 14, and electrode 17 in place to minimize the effects of motion. During operation, the cable 18 snaps into a plastic header 16 disposed on a top portion
of the patch sensor 20. Both the cable 18 and header 16 include matched electrical leads that supply power and ground to the LEDs 10, 12, photodetector 14, and electrode 19. The cable 18 and header 16 additionally supply a high-frequency electrical signal to the electrode that helps generate the electrical waveform. When the patch sensor 20 is not measuring optical and electrical waveforms (e.g., when the patient is sleeping), the cable 18 unsnaps from the header 16, while the sensor 20 remains adhered to the patient’s skin. In this way a single sensor can be used for several days. After use, the patient removes and then discards the sensor 20.

[0030] To measure blood pressure, heart rate, and pulse oximetry, the LEDs 10, 12 generate, respectively, red and infrared radiation that irradiates an underlying artery. Blood volume increases and then decreases as the heart pumps blood through the patient’s artery. Blood cells within the blood absorb and transmit varying amounts of the red and infrared radiation depending on the blood volume and how much oxygen bonds to the cells’ hemoglobin. The photodetector 14 detects a portion of the radiation that reflects off an underlying artery, and in response sends a radiation-induced photocurrent to an analog-to-digital converter embedded within the processing module. The analog-to-digital converter digitizes the photocurrent to generate a time-dependent optical waveform for each wavelength. In addition, the microprocessor analyzes waveforms generated at both red and infrared wavelengths, and compares a ratio of the relative absorption to a calibration table coded in its firmware to determine pulse oximetry. The microprocessor additionally analyzes the time-dependent properties of one of the optical waveforms to determine the patient’s heart rate.

[0031] Concurrent with measurement of the optical waveform, the electrode 19 detects an electrical impulse from the patient’s skin that the microprocessor processes to generate an electrical waveform. The electrical impulse is generated each time the patient’s heart beats.

[0032] The patch sensor 20 preferably has a diameter, ‘D’, ranging from 0.5 centimeter (‘cm’) to 10 cm, more preferably from 1.5 cm to 3.0 cm, and most preferably 2.5 cm. The patch sensor 20 preferably has a thickness, ‘T’, ranging from 1.0 millimeter (‘mm’) to 3 mm, more preferably from 1.0 mm to 1.5 mm, and most preferably 1.25 mm. The patch sensor 20 preferably includes a body composed of a polymeric material such as a neoprene rubber. The body is preferably colored to match a patient’s skin color, and is preferably opaque to reduce the affects of ambient light. The body is preferably circular in shape, but can also be non-circular, e.g., an oval, square, rectangular, triangular or other shape.

[0033] FIG. 2 shows both optical 31 and electrical 32 waveforms generated by the patch sensor of FIGS. 1A and 1B. Following a heartbeat, the electrical impulse travels essentially instantaneously from the patient’s heart to the patch sensor, where the electrode detects it to generate the electrical waveform 32. At a later time, a pressure wave induced by the same heartbeat propagates through the patient’s arteries and arrives at the sensor, where the LEDs and photodetector detect it as described above to generate the optical waveform 31. The propagation time of the electrical impulse is independent of blood pressure pressure, whereas the propagation time of the pressure wave depends strongly on pressure, as well as mechanical properties of the patient’s arteries (e.g., arterial size, stiffness). The microprocessor runs an algorithm that analyzes the time difference ΔT between the arrivals of these signals, i.e., the relative occurrence of the optical 31 and electrical 32 waveforms as measured by the patch sensor. Calibrating the measurement (e.g., with a conventional blood pressure cuff) accounts for patient-to-patient variations in arterial properties, and correlates ΔT to both systolic and diastolic blood pressure. This results in a calibration table. During an actual measurement, the calibration source is removed, and the microprocessor analyzes ΔT along with other properties of the optical and electrical waveforms and the calibration table to calculate the patient’s real-time blood pressure.

[0034] The microprocessor can analyze other properties of the optical waveform 31 to augment the above-mentioned measurement of blood pressure. For example, the waveform can be ‘fit’ using a mathematical function that accurately describes the waveform’s features, and an algorithm (e.g., the Marquardt-Levenberg algorithm) that iteratively varies the parameters of the function until it best matches the time-dependent features of the waveform. In this way, blood pressure-dependent properties of the waveform, such as its width, rise time, fall time, and area, can be calibrated as described above. After the calibration source is removed, the patch sensor measures these properties along with ΔT to determine the patient’s blood pressure.

[0035] Methods for processing the optical and electrical waveforms to determine blood pressure are described in the following co-pending patent applications, the entire contents of which is incorporated by reference: 1) CUFFLESS BLOOD-PRESSURE MONITOR AND ACCOMPANYING WIRELESS, INTERNET-BASED SYSTEM (U.S. Ser. No. 10/709,015; filed Apr. 7, 2004); 2) CUFFLESS SYSTEM FOR MEASURING BLOOD PRESSURE (U.S. Ser. No. 10/709,014; filed Apr. 7, 2004); 3) CUFFLESS BLOOD PRESSURE MONITOR AND ACCOMPANYING WEB SERVICES INTERFACE (U.S. Ser. No. 10/810,237; filed Mar. 26, 2004); 4) VITAL-SIGN MONITOR FOR ATHLETIC APPLICATIONS (U.S. Ser. No.; filed Sep. 13, 2004); 5) CUFFLESS BLOOD PRESSURE MONITOR AND ACCOMPANYING WIRELESS MOBILE DEVICE (U.S. Ser. No. 10/967,511; filed Oct. 18, 2004); and 6) BLOOD PRESSURE MONITORING DEVICE FEATURING A CALIBRATION-BASED ANALYSIS (U.S. Ser. No. 10/967,610; filed Oct. 18, 2004).

[0036] FIG. 3 shows a preferred configuration of electronic components featured within the processing module 50. A data-processing circuit 17 connects to an optical signal processing circuit 35 that powers both the LEDs and the photodetector, and additionally processes radiation-induced photocurrent generated by the photodetector. The data-processing circuit 17 typically includes a microprocessor 45, which in turn includes an embedded analog-to-digital converter 46 that digitizes signals to generate both the electrical and optical waveforms. In a similar manner, the data-processing circuit 17 controls an RF source 18 for the electrode. To receive inputs from wireless devices, the processing module 50 includes a Bluetooth™ wireless transceiver 38 that receives information through an antenna 26 from a matched transceiver embedded within an external component. The processing module 50 can also include a
liquid crystal display (‘LCD’) 42 that displays blood-pressure information for the user or patient. In another embodiment, the data-processing circuit 17 avails calculated information through a serial port 40 to an external personal computer, which then displays and analyzes the information using a client-side software application. A battery 37 powers all the electrical components within the processing module, and is preferably a metal hydride battery (generating 3.7V) that can be recharged through a battery-recharge interface 44.

[0037] Referring to FIGS. 4A and 4B, in embodiments the patch sensor 20 is head-mounted and attaches through a cable 18 to a processing module 50 worn on the patient’s belt. Preferably the sensor attaches to the patient’s forehead 52, underneath the patient’s ear, on the back of the patient’s neck, or to any other location on the patient’s head that is on or near an artery. Typically the patient’s head undergoes relatively little motion compared to other parts of the patient’s body (e.g., the hands), and thus attaching the sensor to this region reduces the negative affects of motion-related artifacts.

[0038] In another embodiment, shown in FIG. 5, the sensor 20 includes a wireless transceiver 70 (e.g., a Bluetooth transceiver) that communicates with a matched wireless transceiver 71 in the processing module 50 through a wireless link 24. In this embodiment the sensor 20 additionally includes a battery 73 that powers the wireless transceiver 70 and all the sensing components therein. During operation, the battery-powered sensor 20 collects the optical and electrical waveforms as described above, and transmits these with the wireless transceiver 70 to the transceiver 71 in the processing component 50. The processing module 50 then processes the waveforms as described above to determine the patient’s vital signs.

[0039] FIG. 6 shows a preferred embodiment of an Internet-based system 53 that operates in concert with the adhesive patch sensor 20 and processing module 50 to send information from a patient to a hand-held wireless device 15. The wireless device 15 then sends the information through a wireless network 54 to a website 66 hosted on an Internet-based host computer system 57. A secondary computer system 69 accesses the website 66 through the Internet 67. The system 53 functions in a bidirectional manner, i.e., the processing module 50 can both send and receive data. Most data flows from the processing module 20 to the website 66; using the same network, however, the device can also receive data (e.g., ‘requests’ to measure data or text messages) and software upgrades.

[0040] A wireless gateway 55 connects to the wireless network 54 and receives data from one or more wireless devices 15, as discussed below. The wireless gateway 55 additionally connects to a host computer system 57 that includes a database 63 and a data-processing component 68 for, respectively, storing and analyzing the data. The host computer system 57, for example, may include multiple computers, software pieces, and other signal-processing and switching equipment, such as routers and digital signal processors. The wireless gateway 55 preferably connects to the wireless network 54 using a TCP/IP-based connection, or with a dedicated, digital leased line (e.g., a frame-relay circuit or a digital line running an X.25 or other protocols). The host computer system 57 also hosts the website 66 using conventional computer hardware (e.g., computer servers for both a database and the website) and software (e.g., web server and database software).

[0041] During typical operation, the patient continuously wears the patch sensor 20 for a period of time ranging from a 1-2 days to weeks. Alternatively, the patient may wear the sensor 20 for shorter periods of time, e.g. just a few hours. For example, the patient may wear the sensor during a brief hospital stay, or during a medical checkup. To view information sent from the processing module, the patient or professional accesses a user interface hosted on the website 66 through the Internet 67 from the secondary computer system 69. The system 53 may also include a call center, typically staffed with medical professionals such as doctors, nurses, or nurse practitioners, whom access a care-provider interface hosted on the same website 66.

[0042] In an alternate embodiment, the host computer system 57 includes a web services interface 70 that sends information using an XML-based web services link to a secondary, web-based computer application 71. This application 71, for example, could be a data-management system operating at a hospital.

[0043] The processing module 50 can optionally be used to determine the patient’s location using embedded position-location technology (e.g., GPS, network-assisted GPS, or 802.11-based location system). In situations requiring immediate medical assistance, the patient’s location, along with relevant medical data collected by the blood pressure monitoring system, can be relayed to emergency response personnel.

[0044] In a related embodiment, the processing module 50 and wireless device may use a ‘store and forward’ protocol wherein the processing module 50 stores information when the wireless device is out of wireless coverage, and then sends this information to the wireless device when it roams back into wireless coverage.

[0045] In an alternate embodiment of the invention, the processing module and patch sensor are used within a hospital, and the processing module includes a short-range wireless link (e.g., a module operating Bluetooth™, 802.11a, 802.11b, 802.1g, or 802.15.4 wireless protocols) that sends vital-sign information to an in-hospital network. In this embodiment, a nurse working at a central nursing station can quickly view the vital signs of the patient using a simple computer interface.

[0046] Still other embodiments are within the scope of the following claims.

What is claimed is:

1. A system for monitoring blood pressure, the system comprising:
   a monitoring device comprising an adhesive patch sensor component that generates an optical signal and a processing component for processing the optical signal with calibration information to obtain blood pressure information; and a computer system configured to receive and display the blood-pressure information.

2. The system of claim 1, wherein the optical system comprises at least one LED and a photodiode.

3. The system of claim 2, wherein the processing component comprises a microprocessor that processes the opti-
cal waveform along with the calibration information to determine the blood-pressure information.

4. The system of claim 1, wherein the adhesive patch sensor component further comprises an electrode that measures an electrical waveform.

5. The system of claim 4, wherein the processing component further comprises a microprocessor that processes both the optical and electrical waveforms to determine the blood-pressure information.

6. The system of claim 1, wherein the adhesive patch sensor further comprises a short-range wireless transmitter.

7. The system of claim 6, wherein the short-range wireless transmitter is a transmitter that operates a protocol based on Bluetooth™, 802.11a, 802.11b, 802.1g, or 802.15.4.

8. The system of claim 1, wherein the monitoring device further comprises a short-range wireless component that operates a wireless protocol based on Bluetooth™, 802.11a, 802.11b, 802.1g, or 802.15.4.

9. The system of claim 1, wherein the processing component further comprises a wireless transmitter that wirelessly transmits the blood pressure information over a terrestrial wireless network.

10. The system of claim 1, wherein the processing component further analyzes the optical signal to determine pulse oximetry and heart rate.

11. The system of claim 1, where in adhesive patch sensor component comprises and adhesive component configured to attach to a patient’s head.

12. A monitoring device for monitoring a patient’s blood pressure, the monitoring device comprising: a head-mounted component comprising a body and an optical device positioned within the body for measuring blood pressure from the patient’s artery, the body having an adhesive on an exterior surface for adhesively securing the body to the patient’s head; and, means for wirelessly transmitting a signal representative of the patient’s blood pressure.

13. The monitoring device according to claim 12, further comprising means for transmitting the signal to a network.

14. The monitoring device according to claim 12, wherein the optical device comprises a first LED capable of radiating light at a wavelength of approximately 600-800 nanometers, a second LED capable of radiating light at a wavelength of approximately 900-1200 nanometers, and a photodetector capable of detecting reflected light originating from the first LED and the second LED.

15. A method for measuring blood pressure from a patient, the method comprising: attaching a head-mounted component of a monitoring device to the head of a patient; generating light from a light source within the head-mounted component, the light directed at an artery of the patient; absorbing reflected light originating from the light source with a photodetector positioned within the head-mounted component; sending a signal representative of the absorption rate of the reflected light, the signal sent from the photodetector to a processing component; and processing the signal with the processing component to determine a blood pressure value for the patient.

16. The method according to claim 15 wherein sending the signal comprises transmitting a wireless signal from the head-mounted component to a wireless transceiver within the processing component.

17. The method according to claim 15 further comprising wirelessly sending blood pressure information over a wireless network.

18. The method according to claim 15 wherein the head-mounted monitoring component comprises a polymer body with adhesive on an exterior surface for adhesively attaching the head-mounted monitoring component to the patient’s head, the light source and the photodetector positioned within the polymer body.