typically prescribed for relatively short periods of time, e.g. for a time period ranging from a few days to several weeks. They are typically wireless, and usually include technologies such as Bluetooth® transceivers to transmit information over a short range to a second device, which typically includes a cellular radio to transmit the information to a web-based system.

[0005] Bioimpedance medical devices measure SV, CO, and FLUIDS by sensing and processing time-dependent ECG and IPG waveforms. Typically, these devices connect to patients through disposable electrodes adhered at various locations on a patient's body. Disposable electrodes that measure ECG and IPG waveforms are typically worn on the patient's chest or legs and include: i) a conductive hydrogel that contacts the patient; ii) a Ag/AgCl-coated eyelet that contacts the hydrogel; iii) a conductive metal post that connects the eyelet to a lead wire or cable extending from the device; and iv) an adhesive backing that adheres the electrode to the patient. Medical devices that measure BP, including systolic (SYS), diastolic (DIA), and mean (MAP) BP, typically use cuff-based techniques called oscillometry or auscultation, or pressure-sensitive catheters than are inserted in a patient's arterial system. Medical devices that measure SpO2 are typically optical sensors that clip onto a patient's finger or earlobes, or attach through an adhesive component to the patient's forehead.

SUMMARY

[0005a] In an aspect, the present disclosure refers to a sensor for measuring a photoplethysmogram (PPG) waveform from a patient, the sensor comprising: a primary housing worn entirely on the patient's chest, wherein the primary housing includes two halves separated by a rubber gasket; and a secondary housing adapted to be located adjacent to a shoulder of the patient, the secondary housing coupled to the primary housing via a flexible wire, wherein the secondary housing includes: a heating element attached to the bottom surface of the secondary housing so that it contacts and heats an area of the patient's shoulder when the secondary housing is worn on the patient's shoulder; an optical system located on a bottom surface of the secondary housing and proximal to the heating element, the optical system comprising a light source configured to generate optical radiation that irradiates the area of the patient's shoulder; a temperature sensor in direct contact with the

heating element; a closed-loop temperature controller comprised within the secondary housing and in electrical contact with the heating element and the temperature sensor, the closed-loop temperature controller configured to receive a signal from the temperature sensor and, in response, control an amount of heat generated by the heating element; and a photodetector comprised by the optical system and configured to generate a PPG waveform by detecting radiation that reflects off the area of the patient's shoulder after it is heated by the heating element.

[0006b] In another aspect, the present disclosure refers to a sensor for measuring a photoplethysmogram (PPG) waveform from a patient, the sensor comprising: a primary housing worn entirely on the patient's chest wherein the primary housing includes two halves separated by a rubber gasket; and a secondary housing adapted to be located adjacent to a shoulder of the patient, the secondary housing coupled to the primary housing via a flexible wire, wherein the secondary housing includes: a heating element attached to a bottom surface of the secondary housing so that it contacts and heats an area of the patient's shoulder when the secondary housing is worn on the patient's shoulder; a temperature sensor in direct contact with the heating element; a closed-loop temperature controller comprised within the secondary housing and in electrical contact with the heating element and the temperature sensor, the closed-loop temperature controller configured to receive a signal from the temperature sensor and, in response, control an amount of heat generated by the heating element; and an optical system comprised by the secondary housing and located proximal to the heating element, the optical system comprising a light source configured to generate optical radiation that irradiates the area of the patient's shoulder, and a photodetector configured to generate a PPG waveform by detecting radiation that reflects off the area after it is heated by the heating element.

[0006] In view of the foregoing, it would be beneficial to improve the monitoring of patients in hospitals, clinics, and the home with a patch sensor, like that described herein, that non-invasively measures vital signs such as HR, HRV, RR, SpO2, TEMP, and BP, along with complex hemodynamic parameters such as SV, CO, and FLUIDS. The patch sensor adheres to a patient's chest and continuously and non-invasively measures the above-mentioned parameters without cuffs and wires. In this way, it simplifies traditional protocols for taking such measurements, which typically involve multiple machines and can take several minutes to accomplish. The patch sensor wirelessly transmits information

patients. The patch sensor can additionally monitor patients from locations outside the hospital.

[0007] More particularly, the present disclosure features a chest-worn patch sensor that measures the following parameters from a patient: HR, PR, SpO2, RR, BP, TEMP, FLUIDS, SV, CO, and a set of parameters sensitive to blood pressure and systemic vascular resistance called pulse arrival time (PAT) and vascular transit time (VTT).

[0008] The patch sensor also includes a motion-detecting accelerometer, from which it can determine motion-related parameters such as posture, degree of motion, activity level, respiratory-induced heaving of the chest, and falls. Such parameters could determine, for example, a patient's posture or movement during a hospital stay. The patch sensor can operate additional algorithms to process the motion-related parameters to measure vital signs and hemodynamic parameters when motion is minimized and below a predetermined threshold, thereby reducing artifacts. Moreover, the patch sensor estimates motion-related parameters such as posture to improve the accuracy of calculations for vital signs and hemodynamic parameters.

[0009] Disposable electrodes on a bottom surface of the patch sensor secure it to the patient's body without requiring bothersome cables. The electrodes measure ECG and IPG waveforms. They easily connect (and disconnect) to circuit boards contained within the sensor by means of magnets that are electrically connected to the circuit boards to provide signal-conducting electrical couplings. Prior to use, the electrodes are simply held near the circuit boards, and magnetic attraction causes the electrode patches to snap into proper position, thereby ensuring proper positioning of the electrodes on the patient's body.

[00010] Using light-emitting diodes (LEDs) operating in the red (e.g. 660 nm) and infrared (e.g. 900 nm) spectral regions, the patch sensor measures SpO2 by pressing lightly against capillary beds in the patient's chest. A heating element on the bottom surface of the patch sensor contacts the patient's chest and gently warms the underlying skin, thereby increasing perfusion of the tissue. Operating with reflection-mode optics, the patch sensor measures PPG waveforms with both red and infrared wavelengths. SpO2 is processed from alternating and static components of these waveforms, as is described in more detail below.

[00011] The patch sensor measures all of the above-mentioned properties while featuring a comfortable, easy-to-wear form factor. It is lightweight (about 20 grams) and powered with a rechargeable battery. During use, it rests on the patient's chest, where the disposable electrodes hold it in place, as described in more detail below. The patient's chest is a location that is unobtrusive, comfortable, removed from the hands, and able to hold the sensor without being noticeable to the patient. It is also relatively free of motion compared to appendages such as the hands and fingers, and thus a sensor affixed to the chest region minimizes motion-related artifacts. Such artifacts are compensated for, to some degree, by the accelerometer within the sensor. And because the patch sensor is a small and therefore considerably less noticeable or obtrusive than various other physiological sensor devices, emotional discomfort over wearing a medical device over an extended period of time is reduced, thereby fostering long-term patient compliance for use of this device within a monitoring regimen.

[00012] Given the above, in one example, the present disclosure provides a patch sensor for simultaneously measuring BP and SpO2 from a patient. The patch sensor features a sensing portion having a flexible housing that is worn entirely on the patient's chest and encloses a battery, wireless transmitter, and all the sensor's sensing and electronic components. The sensor measures ECG, IPG, PPG, and PCG waveforms, and collectively processes these determine BP and SpO2. The sensor that measures PPG waveforms includes a heating element to increase perfusion of tissue on the chest.

[00013] On its bottom surface, the flexible housing includes an analog optical system, located proximal to one pair of the electrode contact points, that features a light source that generates radiation in both the red and infrared spectral ranges. This radiation separately irradiates a portion of the patient's chest disposed underneath the flexible housing. A photodetector detects the reflected radiation in the different spectral ranges to generate analog red-PPG and infrared-PPG waveforms.

[00014] A digital processing system disposed within the flexible housing includes a microprocessor and an analog-to-digital converter, and is configured to: 1) digitize the analog ECG waveform to generate a digital ECG waveform, 2) digitize the analog impedance waveform to generate a digital impedance waveform, 3) digitize the analog red-PPG waveform to generate a digital red-PPG waveform, 4) digitize the analog infrared-PPG waveform to generate a digital infrared-PPG waveform, and 5) digitize the

analog PCG waveform to generate a digital PCG waveform. Once these waveforms are digitized, numerical algorithms operating in embedded computer code called 'firmware' process them to determine the parameters described herein.

[00015] In another example, the present disclosure provides a patch sensor for measuring a PPG waveform from a patient. The patch sensor includes a housing worn entirely on the patient's chest, and a heating element attached to the bottom surface of the housing so that, during use, it contacts and heats an area of the patient's chest. An optical system is located on a bottom surface of the housing and proximal to the heating element, and includes a light source that generates optical radiation that irradiates the area of the patient's chest during a measurement. The sensor also features a temperature sensor in direct contact with the heating element, and a closed-loop temperature controller within the housing and in electrical contact with the heating element and the temperature sensor. During a measurement, the closed-loop temperature controller receives a signal from the temperature sensor and, in response, controls an amount of heat generated by the heating element. A photodetector within the optical system generates the PPG waveform by detecting radiation that reflects off the area of the patient's chest after it is heated by the heating element.

[00016] Heating tissue that yields the PPG waveform typically increases blood flow (i.e. perfusion) to the tissue, thereby increasing the amplitude and signal-to-noise ratio of the waveform. This is particularly important for measurements made at the chest, where signals are typically significantly weaker than those measured from more conventional locations, such as the fingers, earlobes, and forehead.

[00017] In examples, the heating element features a resistive heater, such as a flexible film, metallic material, or polymeric material (e.g. Kapton®) that may include a set of embedded electrical traces that increase in temperature when electrical current passes through them. For example, the electrical traces may be disposed in a serpentine pattern to maximize and evenly distribute the amount of heat generated during a measurement. In other examples, the closed-loop temperature controller includes an electrical circuit that applies an adjustable potential difference to the resistive heater that is controlled by a microprocessor. Preferably, the microcontroller adjusts the potential difference it applies to the resistive heater so that its temperature is between 40-45°C.

[00018] In examples, the flexible-film heating element features an opening that transmits optical radiation generated by the light source so that it irradiates an area of the patient's chest disposed underneath the housing. In similar examples, the flexible film features a similar opening or set of openings that transmit optical radiation reflected from the area of the patient's chest so that it is received by the photodetector.

[00019] In still other examples, the housing further includes an ECG sensor that features a set of electrode leads, each configured to receive an electrode, that connect to the housing and electrically connect to the ECG sensor. For example, a first electrode lead is connected to one side of the housing, and a second electrode lead is connected to an opposing side of the housing. During a measurement, the ECG sensor receives ECG signals from both the first and second electrodes leads, and, in response, processes the ECG signals to determine an ECG waveform.

[00020] In another example, the present disclosure provides a sensor for measuring PPG and ECG waveforms from a patient that is also worn entirely on the patient's chest. The sensor features an optical sensor, heating element, and temperature sensor similar to that described above. The sensor also includes a closed-loop temperature controller within the housing and in electrical contact with the heating element, the temperature sensor, and the processing system. The closed-loop temperature controller is configured to: 1) receive a first signal from the temperature sensor; 2) receive a second signal from the processing system corresponding to the second fiducial marker; 3) collectively process the first and second signals to generate a control parameter; and 4) control an amount of heat generated by the heating element based on the control parameter.

[00021] In examples, a software system included in the processing system determines a first fiducial marker within the ECG waveform that is one of a QRS amplitude, a Q-point, a R-point, an S-point, and a T-wave. Similarly, the software system determines a second fiducial marker that is one of an amplitude of a portion of the PPG waveform, a foot of a portion of the PPG waveform, and a maximum amplitude of a mathematical derivative of the PPG waveform.

[00022] In examples, the closed-loop temperature controller features an adjustable voltage source, and is configured to control an amount of heat generated by the heating

element by adjusting the voltage source, e.g. the amplitude or frequency of a voltage generated by the voltage source.

[00023] In another example, the present disclosure provides a similar chest-worn sensor that measures PPG waveforms from the patient, and from these SpO2 values. The sensor features a similar heating element, temperature, closed-loop temperature controller, and optical system as described above. Here, the optical system generates optical radiation in both the red and infrared spectral regions. The sensor also includes an ECG sensor with at least two electrode leads and an ECG circuit that generates an ECG waveform. During a measurement, a processing system featuring a software system analyzes the ECG waveform to identify a first fiducial marker, and based on the first fiducial marker, identifies a first set of fiducial markers within the red PPG waveform, and a second set of fiducial markers within the infrared PPG waveform. The processing system then collectively processes the first and second set of fiducial markers to generate the SpO2 value.

[00024] In the present disclosure, for example, the first set of fiducials identified by the software system features an amplitude of a baseline of the red PPG waveform (RED(DC)) and an amplitude of a heartbeat-induced pulse within the red PPG waveform (RED(AC)), and the second set of fiducials identified by the software system features an amplitude of a baseline of the infrared PPG waveform (IR(DC)) and an amplitude of a heartbeat-induced pulse within the infrared PPG waveform (IR(AC)). The software system can be further configured to generate the SpO2 value from a ratio of ratios (R) by analyzing the RED(DC), RED(AC), IR(DC), and IR(AC) using the following equations, or mathematical equivalents thereof:

$$R = \frac{RED(AC)/RED(DC)}{IR(AC)/IR(DC)}$$

$$SpO2 = \frac{k_1 - k_2 \times R}{k_3 - k_4 \times R}$$

where k_1, k_2, k_3, and k_4 are pre-determined constants. Typically, these constants are determined during a clinical study called a 'breathe-down study' using a group of patients. During the study, the concentration of oxygen supplied to the patients is gradually lowered in sequential 'plateaus' so that their SpO2 values changes from normal values

(near 98-100%) to hypoxic values (near 70%). As the concentration of oxygen is lowered, reference SpO2 values are typically measured at each plateau with a calibrated oximeter or a machine that measures oxygen content from aspirated blood. These are the 'true' SpO2 values. R values are also determined at each plateau from PPG waveforms measured by the patch sensor. The pre-determined constants k_1, k_2, k_3, and k_4 can then be determined by fitting these data using equations shown above.

[00025] In other examples, the invention provides a chest-worn sensor similar to that described above, that also includes an acoustic sensor for measuring PCG waveforms. Here, the sensor is mated with a single-use component that temporarily attaches to the sensor's housing and features a first electrode region positioned to connect to the first electrode contact point, a second electrode region positioned to connect to the second electrode contact point, and an impedance-matching region positioned to attach to the acoustic sensor.

[00026] In examples, the impedance-matching region comprises a gel or plastic material, and has an impedance at 100 kHz of about 220 Ω. The acoustic sensor can be a single microphone or a pair of microphones. Typically, the sensor includes an ECG sensor that yields a signal that is then processed to determine a first fiducial point (e.g. a Q-point, R-point, S-point, or T-wave of a heartbeat-induced pulse in the ECG waveform). A processing system within the sensor processes the PCG waveform to determine the second fiducial point, which is either the S1 heart sound or S2 heart sound associated with a heartbeat-induced pulse in the PCG waveform. The processing system then determines a time difference separating the first fiducial point and the second fiducial point, and uses this time difference to determine the patient's blood pressure. Typically a calibration measurement made by a cuff-based system is used along with the time difference to determine blood pressure.

[00027] In examples, the processor is further conjured to determine a frequency spectrum of the second fiducial point (using, e.g., a Fourier Transform), and then uses this to determine the patient's blood pressure.

[00028] In yet another example, the present disclosure provides a chest-worn sensor similar to that described above. Here, the sensor features an optical system, located on a bottom surface of the sensor's housing, that includes: 1) a light source that generates optical radiation that

CLAIMS

1. A sensor for measuring a photoplethysmogram (PPG) waveform from a patient, the sensor comprising:

a primary housing worn entirely on the patient's chest, wherein the primary housing includes two halves separated by a rubber gasket; and

a secondary housing adapted to be located adjacent to a shoulder of the patient, the secondary housing coupled to the primary housing via a flexible wire, wherein the secondary housing includes:

a heating element attached to the bottom surface of the secondary housing so that it contacts and heats an area of the patient's shoulder when the secondary housing is worn on the patient's shoulder;

an optical system located on a bottom surface of the secondary housing and proximal to the heating element, the optical system comprising a light source configured to generate optical radiation that irradiates the area of the patient's shoulder;

a temperature sensor in direct contact with the heating element;

a closed-loop temperature controller comprised within the secondary housing and in electrical contact with the heating element and the temperature sensor, the closed-loop temperature controller configured to receive a signal from the temperature sensor and, in response, control an amount of heat generated by the heating element; and

a photodetector comprised by the optical system and configured to generate a PPG waveform by detecting radiation that reflects off the area of the patient's shoulder after it is heated by the heating element.

2. The sensor of claim 1, wherein the heating element comprises a resistive heater.

3. The sensor of claim 2, wherein the resistive heater is a flexible film.

4. The sensor of claim 3, wherein the resistive heater comprises a set of electrical traces configured to increase in temperature when electrical current passes through them.

5. The sensor of claim 3, wherein the flexible film is a polymeric material.

6. The sensor of claim 2, wherein the closed-loop temperature controller comprises an electrical circuit that applies a potential difference to the resistive heater.

7. The sensor of claim 6, wherein the closed-loop temperature controller comprises a microprocessor configured to process the signal from the temperature sensor, and, in response, adjust the potential difference it applies to the resistive heater.

8. The sensor of claim 7, wherein the microprocessor comprises computer code configured to process the signal from the temperature sensor, and, in response, adjust the potential difference it applies to the resistive heater so that its temperature is between 40-45^{o}C.

9. The sensor of claim 3, wherein the flexible film comprises an opening that transmits optical radiation generated by the light source so that it irradiates an area of the patient's shoulder disposed underneath the secondary housing.

10. The sensor of claim 3, wherein the flexible film comprises an opening that transmits optical radiation reflected from the area of the patient's shoulder so that it is received by the photodetector.

11. The sensor of claim 1, wherein the primary housing further comprises an electrocardiogram (ECG) sensor.

12. The sensor of claim 11, where a set of electrode leads, each configured to receive an electrode, connect to the primary housing and electrically connect to the ECG sensor.

13. The sensor of claim 12, wherein a first electrode lead is connected to one side of the primary housing, and a second electrode lead is connected to an opposing side of the primary housing.

14. The sensor of claim 11, wherein the ECG sensor receives an ECG signal from at least one of a first and second electrodes leads, and, in response, processes the ECG signal to determine an ECG waveform.

15. A sensor for measuring a photoplethysmogram (PPG) waveform from a patient, the sensor comprising:

a primary housing worn entirely on the patient's chest wherein the primary housing includes two halves separated by a rubber gasket; and

a secondary housing adapted to be located adjacent to a shoulder of the patient, the secondary housing coupled to the primary housing via a flexible wire, wherein the secondary housing includes:

a heating element attached to a bottom surface of the secondary housing so that it contacts and heats an area of the patient's shoulder when the secondary housing is worn on the patient's shoulder;

a temperature sensor in direct contact with the heating element;

a closed-loop temperature controller comprised within the secondary housing and in electrical contact with the heating element and the temperature sensor, the closed-loop temperature controller configured to receive a signal from the temperature sensor and, in response, control an amount of heat generated by the heating element; and

an optical system comprised by the secondary housing and located proximal to the heating element, the optical system comprising a light source configured to generate optical radiation that irradiates the area of the patient's shoulder, and a photodetector configured to generate a PPG waveform by detecting radiation that reflects off the area after it is heated by the heating element.

16. The sensor of claim 15, wherein the heating element comprises a resistive heater.

17. The sensor of claim 16, wherein the resistive heater is a flexible film.

18. The sensor of claim 17, wherein the resistive heater comprises a set of electrical traces configured to increase in temperature when electrical current passes through them.

19. The sensor of claim 17, wherein the flexible film is a polymeric material.

20. The sensor of claim 16, wherein the closed-loop temperature controller comprises an electrical circuit that applies a potential difference to the resistive heater.

21. The sensor of claim 20, wherein the closed-loop temperature controller comprises a microprocessor configured to process the signal from the temperature sensor, and, in response, adjust the potential difference it applies to the resistive heater.

22. The sensor of claim 21, wherein the microprocessor comprises computer code configured to process the signal from the temperature sensor, and, in response, adjust the potential difference it applies to the resistive heater so that its temperature is between 40-45^{o}C.

23. The sensor of claim 17, wherein the flexible film comprises a first opening that transmits optical radiation generated by the light source so that it irradiates the area of the patient's shoulder disposed underneath the secondary housing.

24. The sensor of claim 17, wherein the flexible film comprises a second opening that transmits optical radiation reflected from the area of the patient's shoulder so that it is received by the photodetector.

25. The sensor of claim 15, wherein the primary housing further comprises an electrocardiogram (ECG) sensor.

26. The sensor of claim 25, where a set of electrode leads, each configured to receive an electrode, connect to the primary housing and electrically connect to the ECG sensor.

27. The sensor of claim 26, wherein a first electrode lead is connected to one side of the primary housing, and a second electrode lead is connected to an opposing side of the primary housing.

28. The sensor of claim 26, wherein the ECG sensor receives an ECG signal from at least one of a first and second electrodes leads, and, in response, processes the ECG signal to determine an ECG waveform.