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(54) Title: OPTICAL SENSOR FOR HEALTH MONITORING

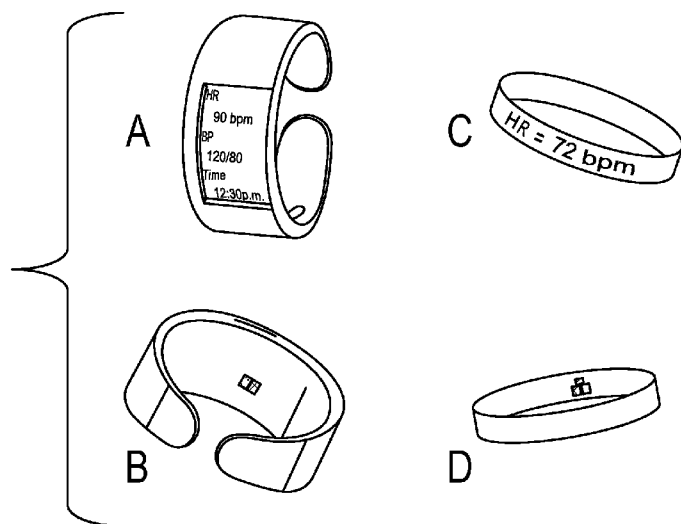


FIG. 10

(57) Abstract: The present invention relates to a device, a system, an algorithm, and a method for cardiac health and fitness monitoring of a person. More particularly, the invention relates to a sensor suitable for remote patient monitoring. The key to widespread acceptance of a remote sensor is to enable it for 'plug- and-play'. The ideal sensor should function out of the box without additional components, and it should provide a direct digital interface to a micro controller. It should also be small, and relatively low cost (few dollars or less).

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OPTICAL SENSOR FOR HEALTH MONITORING

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application Ser. No. 62/006,961, filed on June 3, 2014, which is incorporated herein by reference in its
5 entirety.

TECHNICAL FIELD

[0002] The present invention relates to a device, a system, an algorithm and a method for cardiac health monitoring of a person. More particularly, the invention relates to a sensor suitable for wearable, mobile device (cell phone or tablet) based, and/or implantable devices
10 for remote patient monitoring or health and fitness tracking and logging.

BACKGROUND OF THE INVENTION

[0003] Remote patient monitoring (RPM), also called telehealth or telemonitoring, is a growing trend in modern health care with a multi-billion dollar market. This is useful for monitoring in many chronic diseases, including cardiovascular health, chronic fatigue
15 syndrome, depression, and related ailments, and sleep-related ailments such as insomnia or sleep apnea.

[0004] Remote patient monitoring has an important role in the management of patients at-risk for complications of cardiovascular disease.

[0005] There is an unmet need for convenient 24-hour physiological monitoring. The
20 market of wearable optical sensors and cell phones is growing at an extremely fast pace. One problem facing most current devices is the susceptibility to motion artifacts, skin tone fluctuations, fluctuations in the signal from the tissue with temperature, and general differences in blood and tissue within and across the population. There is interest in developing an optical device capable of measuring heart rate and other physiologic
25 measurements under a wide variety of conditions and during motion.

[0006] Optical fitness and health monitors are being used or investigated for use in almost every mobile device based or wearable device on the market today. The stability of these monitors and the ability to operate in the presence of noise is the biggest challenge

facing all manufacturers. Currently, the majority of optical devices use a single wavelength to measure heart rate. Some of the devices employ two or more detectors or two or more wavelengths but these detectors and wavelengths are used in a static way that does not take into account the changes in the measurement conditions and noise sources from the tissue and blood as noted above. In order to filter out motion artifacts, many devices employ an additional accelerometer to measure motion.

[0007] Currently, most devices show poor performance during motion, with different skin tones, and across varying temperatures which is very critical for a fitness and health monitoring devices. Although various approaches have been tried, there is still no complete solution on the market. There is therefore an unmet need for fitness and health monitoring devices or sensors that are capable of overcoming the disadvantages of currently available devices and sensors.

SUMMARY OF THE INVENTION

[0008] The key to widespread acceptance of a remote sensor is to enable it for 'plug-and-play'. The ideal sensor should function out of the box without additional components, and it should provide a direct digital interface to a microcontroller. It should also be small, and relatively low cost (few dollars or less). The most successful example of a plug and play sensor in recent history is the accelerometer, which has seen rapid, pervasive growth in the smart phone, automotive safety, and home entertainment markets.

[0009] According to a first aspect of the invention, an optical sensor assembly of the invention includes an optical sensor with at least one light emitting source that is capable of emitting light over a range of specific wavelengths, a photo detector sensitive to the range of wavelengths, and permitting reflected light rays to reach the at least one photo detector; and an electronic integrated circuit with an amplifier for amplifying a signal detected by the photo detector, an analog to digital converter, noise reduction and ambient light cancellation circuitry, and a digital interface for communication with a microcontroller. The optical sensor is typically accommodated on a mobile device based or wearable carrier.

[00010] According to further embodiments of the invention, a single sensor may include a plurality of identical or different light emitting sources, a plurality of photodiodes, or both.

[00011] In additional embodiments, several sensors may be placed on a person's skin along a vascular path to obtain data relating to blood flow, blood pressure and artery or vascular stiffness. This type of measurement is an indicator of cardiovascular health. In certain embodiments of the invention, the sensor may be used for heart rate
5 monitoring, blood oxygenation, oxygen consumption, energy expenditure, and caloric burn.

[00012] The present approach measures a different type of signal and noise and attempts to relate it to overcoming the noise in the sample including for example the optical motion artifact, variation in skin color, and variations in temperature. In this approach, two or more wavelengths and two or more detectors are employed and the selection of the main
10 wavelength is performed continuously allowing the device to adjust to the measurement conditions and compensate using common mode noise rejection. The other detector or wavelength(s) would not be as optimal for the current set of conditions and thus will carry differing levels of signal but still experience the same noise such as motion. These detectors or wavelengths can then be used to filter noise such as motion out of the main wavelength.
15 This approach provides a more stable signal across a much wider variety of measurement conditions in addition to motion such as temperature variations and change in skin tone.

[00013] Two or more light sources (i.e. light emitting diodes) are used with one or more photodetector(s). The light sources and photodetectors are placed in a certain formation either next to each other or on different sides of the tissue. The light sources
20 illuminate tissue on the measurement site such as the wrist or finger. Part of the light that propagates through the tissue arrives at the photodetector(s) and is transduced into electrical signals. The electrical signals are conditioned (i.e. filtered, amplified, etc.) and sent to a processing unit either on the same board or on a separate board. This transmission can be wired or wireless. The processing unit selects which detector and wavelength has the better
25 signal and use it as the primary detector or wavelength while the other(s) is (are) used as a measure of motion or other noise artifact. The different processing steps can be performed on one or multiple processing units.

[00014] Further details and advantages of the invention become apparent in the following description of various preferred embodiments by way of the attached drawings, the
30 drawings being included for purely illustrative purposes and are not intended to limit the scope of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[00015] FIG. 1 shows a schematic of an algorithm used for a two wavelength system for heart rate monitoring;

[00016] FIGS. 2A to 2E show the graph of two simulated signals (upper left; 2A) with noise (upper right; 2B) and graphs of the actual and predicted heart rates from the above signals (middle graphs; 2C and 2D) as well as the table of the operation of the algorithm with varying noise (2E);

[00017] FIG. 3A and 3B show two graphs of heart rate predicted from a person starting in the sitting position then running and then back in the sitting position again (top; 3A) and a person resting in the sitting position the whole time (bottom; 3B). The graph shows the ECG signal obtained from the chest strap and used as a standard along with the disclosed signal and algorithm;

[00018] FIGS. 4A and 4B show (Top; 4A) PPG signal collected in vivo from the intestines of a pig using a single wavelength at 630 nm; (Bottom; 4B) shows the same sensor data after using two wavelengths (525 and 630 nm) and applying a correction algorithm. The cardiac pulses in the lower panel are more easily distinguishable from noise;

[00019] FIG. 5 shows Fast Fourier Transform of the optical signal before and after using the correction algorithm;

[00020] FIG. 6 shows a schematic of the different layers of the MC model with a cartoon of skin tissue for comparison;

[00021] FIGS. 7A to 7D show a cartoon showing the different modeled states of the sensor: (top left; 7A) good optical coupling, (top right; 7B) loose sensor, (bottom left; 7C) tilted sensor, and (bottom right; 7D) dark skin. All these configurations were repeated for light and dark skin;

[00022] FIGS. 8A to 8D show changes of optical fluence at the detector for light (M1=1% melanin) and dark (M40=40% melanin) skin as a function of wavelength for three different source to detector separations (d). The bottom right panel (8D) shows the ratio of intensity collected from light and dark skin for each wavelength. Red and NIR wavelength show a much lower variation compared to green wavelengths across skin tones;

[00023] FIGS. 9A and 9B show blood signal levels as a function of wavelength for light (left; 9A) & dark (right; 9B) skin;

[00024] FIGS. 10A to 10D show examples of form factors of wearable devices that can use the described invention. The left column (10A and 10B) shows a rendering of a watch type of device capable of measuring various medical parameters. The right column (11A and 11B) shows a band type device that can be used as a form factor for the proposed sensors. The top row (10A and 10C) shows a view of the display side while the bottom row (10B and 10D) shows the photonics side; and

[00025] FIGS. 11A and 11B shows other potential form factors. The left panel (11A) shows a band-aid equipped with an optical sensor. The ring shown in the right panel (11B) is another potential form-factor and offers many advantages in terms of optical sensing. In particular, this form factor has the potential to perform measurements in both reflection and transmission mode.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[00026] Embodiments of the invention include new technologies for sensing and monitoring heart rate. In certain embodiments, the sensors are capable of monitoring physiological parameters such as blood pressure and pulse oximetry. These technologies may be combined in a single sensor.

[00027] Due to the low price, other potential markets may include consumer fitness (as replacement for straps, watches) and the mobile phone industry (as Bluetooth accessory). According to Berg Insight, the worldwide market for home health monitoring was worth about \$10 billion in 2010.

[00028] Beyond fitness, the health conditions most commonly treated via remote monitoring services include diabetes, cardiac arrhythmia, sleep apnea, and asthma. More than 200 million people in Europe and the US suffer from one or more chronic conditions where remote monitoring would be helpful.

[00029] Light can be used to interrogate tissue and measure changes in the blood volume, oxygenation, heart rate, and even blood pressure within tissue. Current light-based sensors typically only work under certain sets of conditions that are typically

characterized as "resting conditions" but previous light-based sensing techniques do not work as well under "active conditions" or on the "boundary cases". These "active and boundary conditions" include motion levels, skin tone, hydration levels, skin temperature, and other conditions. Changes in any of these conditions, such as increased motion and changes in skin tone, often lead to a decrease in the signal to noise ratio and pose concerns about signal integrity.

[00030] In a first aspect, the device utilizes two or more electronic optical sensors in conjunction with an algorithm to determine a physiological parameter such as a patient's heart rate. In a second aspect, the device uses two or more wavelengths of light signals in conjunction with an algorithm to determine a physiological parameter such as heart rate. In certain embodiments, the algorithm is based on characteristics obtained from theoretical modeling of the light tissue interactions under various conditions. The algorithm specifically selects the light signal that carries the better signal (S1) and uses the other signal(s) (S2) to measure the sources of noise (i.e. motion artifacts) and filters them out of the first signal S1. The performance of an optical sensor depends greatly on the illumination wavelength and/or detected signal path length. Depending on the measurement condition, some wavelengths or detectors outperform others. In embodiments of the claimed invention, by using two or more signals (detector or wavelength), the device is able to work over a broader range of conditions. The signal that performs poorly under a set of conditions is used as a measure of the noise, such as that from motion. The use of a second signal as a noise reference yields better filtration of artifacts than traditional one signal methods or using accelerometer sensors since the noise is measured using the same method as the signal and the artifacts on both channels are directly correlated.

[00031] Depending on the application, more than two signals (wavelengths or detectors) can be used. For example, in certain embodiments, two wavelengths are used to measure a stable heart rate signal. In other embodiments, two detectors are used. In further embodiments, adding one or more additional wavelengths allows the device to perform additional measurements such as oxygen saturation (SpO₂). This unique multi-wavelengths and multi-detectors approach has many applications. One potential market is wearable heart rate monitors or mobile devices for fitness and health applications.

[00032] Embodiments of the sensors are used in a wide variety of conditions including variable skin tones, high heart rates, high motion levels, and variable oxygenation

levels. FIG. 1 shows a schematic of the algorithm in the case of a dual signal system for heart rate monitoring employing two signals such as two detector or two wavelength signals. As set forth in FIG. 1, the algorithm starts by acquiring the two signals, preprocessing them, extracting certain features for use later in the algorithm, and then determining which is the better signal. In the case of an optical photoplethysmography (PPG) sensor used for heart rate detection, the algorithm uses criteria such as the amplitude of the DC component, amplitude of the pulse, the periodicity of the pulse, the shape of the pulse, the frequency of the signal, the variability in the signal and others to quantify the amount of signal of interest carried in each detector or wavelength. The preprocessing methods include filtering in the frequency domain to limit the bandwidth, moving window averaging, and spike removal. The features extracted include power spectral density (PSD) and zero crossing counter (ZCC). The optical signal carrying a lower signal to noise ratio is used as a noise reference to filter out noise such as that due to motion from the other signal(s). The noise from the weaker signal is then used to remove the noise from the stronger signal(s). The filtered signal(s) (are) then used to perform the measurement(s) of interest such as for example, heart rate, SpO₂, or blood pressure.

[00033] The devices of the claimed invention can provide heart rate sensing comparable to commercial reflectance photoplethysmography devices and reflectance pulse oximeters, but in a much more compact package with a printed circuit board and in the presence of a variety of sample noise artifacts. The power consumption is less than for conventional photoplethysmography sensors. This improvement makes it possible to make a 24 hour heart rate sensor integrated in a wearable carrier, and one small enough to be worn unobtrusively in on a finger, ear, etc. Due to the low power consumption, a battery holding a charge for operating the sensor for at least 24 hours can be unobtrusively small. For example, FIGS. 10 and 11 show devices that are integrated in wearable carrier in the form of a finger ring or a wrist band or mobile device. In other embodiments, the device can be placed on a fingertip. Although the capillary bed is smaller than the fingertip, the presence of reflective bone backing formed by the finger bone improves the reflected signal.

[00034] Heart rate sensing can be performed with the sensor with significant improvement in power and accuracy compared to conventional methods. FIG. 8 illustrates changes of optical fluence at the detector for light (M1=1% melanin) and dark (M40=40% melanin) skin as a function of wavelength for three different source to detector separations

(d). The bottom right panel shows the ratio of intensity collected from light and dark skin for each wavelength. Red and NIR wavelength show a much lower variation compared to green wavelengths across skin tones.

[00035] In an embodiment of the invention, the time lag along a blood vessel system, for example, along with a change in amplitude and shape of a pulse wave can give information on restrictions and elasticity of the artery, for example due to plaque on the vessel walls. A sensor of the claimed invention may be used for detecting pulse wave velocity. This approach can be robust to environmental noise and to drift of the sensor. Pulse wave velocity can be correlated with blood pressure. The light travels from the light source through the finger to the blood vessel and tissue, where it is partially reflected. The reflected signal is sensed by one or more photodiodes. The measured quantity is called pulse wave velocity and is correlated with blood pressure and arterial stiffness.

[00036] In certain embodiments of the claimed invention, the device is placed in direct contact with the skin, near a capillary bed. Ideal locations include the fingertip, earlobe, inner ear, wrist or forehead. The light source such as an LED emits light into the tissue, where it experiences diffuse reflection from the tissue. This establishes a reflectance signal at the photodiode.

[00037] In certain embodiments of the claimed invention, the body part such as the finger is placed in direct contact with a mobile device (e.g. cell phone or tablet). The light source such as an LED emits light into the tissue, where it experiences diffuse reflection from the tissue. This establishes a reflectance signal at the photodiode. These light sources and detectors could be on the front or back of the mobile device.

[00038] Multiple photoplethysmography measurements are obtained by placing one or more optical sensors in firm contact with the skin at multiple locations as previously described. In certain embodiments, photoplethysmography data is recorded using a microcontroller.

[00039] In certain embodiments, these technologies are integrated with a Bluetooth module or another suitable wireless technology and with rechargeable batteries, making the sensor assembly wireless and comfortably wearable throughout the day. Beside Bluetooth technology, any other low-power transmission protocol is suitable for communication with a computer for evaluation.

[00040] In an embodiment of the claimed invention, the technology leads to a small wireless heart rate sensor or mobile device heart rate sensor. The technology can be integrated into home health monitoring systems where the information is transmitted wirelessly to the patient's physician, hospital, and other caregivers. It can also be incorporated into the patient's electronic medical record. The low cost wearable heart rate sensor has applications in various fields, such as remote patient monitoring in rural areas, in developing countries or monitoring soldiers in the field. In certain embodiments, a "cloud-based" infrastructure can actively manage cardiovascular health. Using the technology of the claimed invention, cardiovascular parameters can be monitored on a 24-hour ambulatory basis using wearable biosensors, with wireless transmission of relevant data to the patient's electronic medical record. These data will then be available to the patient's physician, providing an effective tool for quantitative assessment, thus providing a means for evidence-based medical management. In emergency situations, notifications can be sent to a medical response team and family members. This model could dramatically reduce the cost of chronic cardiovascular care through earlier detection of impending decompensation, while also improving health outcomes by motivating the patient to actively monitor health and take preventative measures.

[00041] One of several embodiments of the invention involves a health finger ring which can monitor heart rate on a 24 hour basis (FIG. 11B). This device will assess heart rate (and potentially blood pressure) on a continual basis forming the foundation of a remote patient monitoring platform that incorporates time-trending and variability assessment.

[00042] Having demonstrated that the sensor technology is fairly robust, a wireless finger ring combines the sensor with a Bluetooth, or other wireless transmitter linked to an application running on the user's cell phone.

[00043] The sensor and transmitter electronics can be arranged on a printed circuit board using standard software. A mobile application may connect to the ring via Bluetooth, which downloads the photoplethysmography data, displays it on the screen, and uses signal processing to calculate the heart rate. Android is an open-source programming model with built-in libraries for simplifying the programming of Bluetooth and displays. Other operating systems and wireless protocols capable of communicating with a mobile device are also suitable. The ring for slipping the sensor onto a finger may be made of

injection molded plastics or cured elastomers, both of which are inexpensive, compatible with embedded electronics, and flexible to allow for multiple ring sizes.

[00044] The proposed system can be used to monitor physiological activity and health on a continual basis. For example, the low-cost, heart rate sensor could be used to
5 monitor sleep, exercise, and stress levels, enabling patient self-monitoring and driven decision making by health care providers. The key benefits to the proposed approach are i) low cost, so it can be deployed to a large number of patients, ii) the sensor is small and nonintrusive, reducing patient discomfort and thereby increasing patient compliance, iii) it can be used to compensate for sample noise such as motion artifact and skin tone variation,
10 iv) it consumes low power, so it can provide 24 hour operation, and v) data is automatically transmitted wirelessly via Bluetooth, further reducing patient burden. The technology will result in better fitness and new methods to assess efficacy and improve patient compliance to physician-prescribed regimens.

[00045] The technology is suited to be deployed in a cloud-based health
15 monitoring and mentoring framework which integrates remote patient monitoring (RPM) with an online community involving medical caregivers and a social network of the patient's peers. This framework may even be used to treat psychosocial disorders.

[00046] RPM provides quantitative, unbiased data which can be used for managing a wide range of chronic physiological and psychological disorders, including post-
20 traumatic stress disorder, depression, hypertension, heart disease, sleep apnea, work stress, and many other psychosocial and physiological disorders. The small form factor and low power consumption of the proposed device is designed to provide all day use and be transparent to the user, reducing patient burden.

[00047] As a whole, remote patient telemonitoring is widely believed to be a
25 critical step toward managing health care costs, while enhancing patient engagement and treatment compliance, an area of critical national priority given the rising costs of healthcare. Telemonitoring can reduce the total cost of care by reducing emergency and hospital visits, and unnecessary treatment, and is especially well suited for supporting patients with chronic conditions.

[00048] Heart rate variability and blood pressure are powerful indicators of physiological and psychological health, directly correlated to real-time emotional state and psychological resilience.

[00049] Heart rate can be used to track sleep cycles, since both blood pressure
5 and heart rate increase during REM sleep.

[00050] Depressed patients report less physical activity than healthy individuals. Daily exercise can be monitored by increases in heart rate activity, similar to fitness monitors.

[00051] Both blood pressure and heart rate variability are closely linked to
10 mental stress, providing a real time measure. Interestingly, heart rate variability is also an indicator of stress resiliency.

[00052] Pulse oximetry measures blood oxygenation (SpO₂) by comparing the pulsation indices at two wavelengths with known absorbance characteristics in oxygenated vs. deoxygenated blood.

15 WORKING EXAMPLES

[00053] The inventive concepts were tested on multiple optical sensors using the PPG technique. The first set of experiments shows two computer simulated signals with and without noise and the graphs of the actual and predicted heart rates from the above signals as well as the table of how good the algorithm works with varying noise. FIG. 2
20 shows a graph of two simulated signals (upper left) simulated signals with noise (upper right) and graphs of the actual and predicted heart rates from the simulated signals (middle graphs) as well as the table of the operation of the algorithm with varying noise.

[00054] In a second set of experiments an *in vitro* phantom and system were built to mimic the optical properties of skin and blood through the skin. The system was built
25 to not only provide a realistic optical phantom and blood flow system but also had the ability to simulate respiratory motion in the flow stream and body movement noise using a separate motor. A table (Table 1) of heart rate predicted from an optically light pigmented skin phantom shows the signal predicted with the algorithm of FIG. 1 under conditions of varying

flow noise simulating respiration and body movement noise simulated by actually moving the phantom with a motor.

TABLE 1

LIGHT SKIN PHANTOM								
	Test #	Noise	Motor Amp.	Motor Freq.	HR	N/S (%)	SNR	Corr. Coeff. CRHT vs. Real
No Motion	1	0	0	0	80-100	0	Inf	0.974
	2	0.075	0	0	80-100	25	16	0.981
	3	0.15	0	0	80-100	50	4	0.971
	4	0.225	0	0	80-100	75	1.78	0.871
	5	0.27	0	0	80-100	90	1.23	0.627
	6	0.3	0	0	80-100	100	1	0.173
With Motion	7	0.075	1	0.5	80-100	25	16	0.977
	8	0.075	2.5	0.5	80-100	25	16	0.931
	9	0.075	3.75	0.5	80-100	25	16	0.945
	10	0.075	5	0.5	80-100	25	16	0.921

- 5 [00055] Table 1 shows a table of heart rate predicted from an optically light pigmented skin phantom mounted on a motor with simulated blood passing through it compared to the known actual heart rates input by the pump. The table shows varying flow noise simulating respiration without body movement and body movement noise simulated by actually moving the phantom with a motor. Table 2 shows a table of heart rate predicted
- 10 from an optically dark pigmented skin phantom mounted on a motor with simulated blood passing through it compared to the known actual heart rates input by the pump. The table shows varying flow noise simulating respiration without body movement and body movement noise simulated by actually moving the phantom with a motor.

TABLE 2

DARK SKIN PHANTOM								
	Test #	Noise	Motor Amp.	Motor Freq.	HR	N/S (%)	SNR	Corr. Coeff. CRHT vs. Real
No Motion	1a	0	0	0	80-100	0	Inf	0.928
	2a	0.075	0	0	80-100	25	16	0.924
	3a	0.15	0	0	80-100	50	4	0.873
	4a	0.225	0	0	80-100	75	1.78	0.714

DARK SKIN PHANTOM								
	Test #	Noise	Motor Amp.	Motor Freq.	HR	N/S (%)	SNR	Corr. Coff. CRHT vs. Real
With Motion	5a	0.27	0	0	80-100	90	1.23	0.412
	6a	0.3	0	0	80-100	100	1	0.211
	7a	0.075	1	0.5	80-100	25	16	0.975
	8a	0.075	2.5	0.5	80-100	25	16	0.947
	9a	0.075	3.75	0.5	80-100	25	16	0.934
	10a	0.075	5	0.5	80-100	25	16	0.974

[00056] Table 2 shows a similar table of heart rate as in Table 1 predicted with the algorithm but from an optically dark pigmented skin phantom mounted in the same system.

5 [00057] The algorithm was further demonstrated in vivo in which data was collected under resting and sit-run-sit conditions on a person. FIG. 3 shows two graphs of heart rate predicted from a person in the sitting position and sit-run-sit condition. The graph shows the ECG signal obtained from the chest strap and used as the gold standard along with our signal and algorithm.

10 [00058] Another set of experiments consisted of *in vivo* porcine studies to measure the pulse, the DC component, and blood perfusion in the intestine. The sensor used in these studies used a red wavelength (630 nm) and a green wavelength (525 nm). The top panel of FIG. 4 shows the data collected using a single wavelength (630 nm) with a high level of artifacts making it difficult to detect the cardiac pulses. The bottom panel shows the dual
15 wavelength after applying the algorithm described above. As shown below, the signal to noise ratio was doubled after applying the algorithm and the cardiac pulses can be easily recognized.

[00059] To quantify the enhancement in the signal, the Fast Fourier Transform (FFT) of the signals were computed. FIG. 5 shows that the noise peaks in the signal after
20 applying the algorithm decreased. Although there was also a slight decrease in the cardiac cycle peak at 2 Hz, the ratio of the signal (cardiac cycle peak) to the noise/background (all other peaks) increased by 30 to 60%. This indicates an increase in the signal to noise ratio.

[00060] Modeling of sensor performance: The experiments described herein have been performed on different types of tissue. In addition to these experiments, the performance of the sensor on skin was modeled using a Monte Carlo (MC) model. MC models are a standard to model the propagation of light in turbid media such as tissue. An MC model was built to mimic tissue as shown in FIG. 6. The model describes skin tissue as 7 different layers and allows for changing a wide variety of parameters through the modification of the optical and geometrical parameters. These parameters include but are not limited to:

- 1- Tissue Blood content
- 2- Blood distribution
- 3- Blood oxygenation
- 4- Skin tone
- 5- Hematocrit
- 6- Hydration levels
- 7- Skin thickness
- 8- Fat levels

[00061] In addition, the model allows for incorporating noise into the system such as motion. Motion was incorporated by adding a top layer in between the sensor and the tissue. This layer mimics air and its geometry is varied to mimic different types of motion. FIG. 7 shows a schematic of the different configurations of motion.

[00062] The optical fluence collected by the photodetector depends on the wavelength(s) of the light source, the separation between the source and detector, and on the skin tone among other variables. FIG. 8 shows that the fluence of light collected by the photodetector is lower for darker skin tones. However, this drop varies with the source wavelength. The bottom right panel of FIG.8 shows the ratio of the collected fluence in the case of light skin (1% melanin) and dark skin (40% melanin). This ratio ranges between 1000 and 2000 for green wavelengths and drops to less than a 100 for red and Near Infrared (NIR) wavelengths. Using a combination of wavelengths from these two ranges coupled with the described algorithm allows the sensor to acquire good signal levels for all skin tones and reduces the need for a large dynamic range.

[00063] In addition to studying the optical intensity, the amount of blood signal within the collected optical intensity was studied. The signal was defined as the change in intensity from ischemic (no blood) to perfused tissue ($S = I_{\text{ischemia}} - I_{\text{normal}}$). The normalized signal showed that the optimal wavelength that carries the highest level of signal varies with

the melanin content (FIG. 9). This is another reason to use two or more wavelengths to cover these changes.

[00064] The proposed sensor can be used in various form factors. In particular, mobile devices such as cell phones or tablets or wearable devices such as wrist bands, watches, rings, arm bands, inner ear, and band-aids that incorporate optical sensing technologies can benefit greatly from the described invention. FIG. 10 shows three examples of form factors. Smartwatch type device is shown in the first two rows of the left panels, a wrist band type of device is shown in the first two rows of the right panels, and the mobile devices are shown in the third row with the cell phone on the left and tablet on the right. The placement of the sensor and light sources can be varied and the form factors in the figures serve as examples only.

[00065] FIG. 11 shows other potential form factors. The left panel shows a band-aid equipped with an optical sensor. The ring shown in the right panel is another potential form-factor and offers many advantages in terms of optical sensing. In particular, this form factor has the potential to perform measurements in both reflection and transmission mode.

[00066] While the present invention has been described in terms of certain preferred embodiments, it will be understood, of course, that the invention is not limited thereto since modifications may be made to those skilled in the art, particularly in light of the foregoing teachings.

CLAIMS

What is claimed is:

1. An optical sensor assembly with multiple signals and an algorithm for cardiovascular monitoring comprising:
 - 5 signals generated using optical light sources emitting light of at least two wavelengths, signals from one or more photo detectors sensitive to the emitted wavelengths; and electronic circuits capable of processing the signals or communicating them to a device, wherein the device contains an algorithm that uses the signals for real-time noise rejection.
 2. The assembly of claim 1, further comprising:
 - 10 an electronic circuit with an amplifier for amplifying a signal detected by the photo detector, an analog to digital converter, noise reduction and a digital interface for communication with a microcontroller; and a mobile device or wearable carrier accommodating the optical sensor and configured for placing the optical sensor in contact with skin.
 - 15 3. The assembly of claim 1, wherein the light sources are LEDs.
 4. The assembly of claim 1, wherein the emitting light is in the visible range.
 5. The assembly of claim 1, wherein the emitting light is in the near-infrared range.
 6. The assembly of claim 1, further comprising a wireless transmission system and an electronic processor with an operating system compatible with a remote wireless device.
 - 20 7. The assembly of claim 1, wherein the remote wireless device is linked to an application running on a user's mobile device.
 8. The assembly of claim 1, further comprising a battery integrated with the wearable carrier.
 9. The assembly of claim 1, wherein one of the signals performs poorly under a set of conditions and is used as a measure of motion.

10. The assembly of claim 1, wherein the wearable carrier is a finger ring.
11. The assembly of claim 1, wherein the wearable carrier is a wrist band.
12. The assembly of claim 1, wherein the wearable carrier is a watch.
13. The assembly of claim 1, wherein the wearable carrier is an arm-band.
- 5 14. The assembly of claim 1, wherein the wearable carrier is a band-aid.
15. The assembly of claim 1, wherein the carrier is a mobile device.
16. The assembly of claim 1, further comprising a second light source.
17. The assembly of claim 1 configured to perform heart rate monitoring measurements.
18. The assembly of claim 1 configured to perform pulse oximetry measurements.
- 10 19. The assembly of claim 1 configured to perform cuffless blood pressure measurements.
20. The assembly of claim 1 configured to perform fatigue measurements.
21. An optical sensor assembly system comprising a plurality of optical sensor assemblies according to claim 1.
22. A method of sensing biometrical data with an optical sensor assembly system according
15 to claim 1, the method comprising the steps of:

placing at least one optical sensor assembly in a location on skin of a person in the vicinity of
an blood vessel or vessels suited for measuring a pulse from the person's heart;

recording measurement from the optical sensor assembly; and

generating an output that is representative of the measurement.
- 20 23. The method of claim 22, comprising placing a second or third optical sensor assembly in
the same location or different location to perform one or more measurements.
24. The method of claim 23, wherein the one or more measurements is selected from heart
rate monitoring, pulse oximetry, blood pressure and fatigue measurements.

25. The method of claim 22, comprising an algorithm that calculates
- the acquisition of at least two channels of data from either multiple detectors or wavelengths in which both signal and noise is included in those data channels;
- a frequency sweeping approach that reduces the frequency of the data channels' spectrum in the range of 30-240 beat per min to estimate the heart rate;
- 5 a preprocessing approach on the data channels that includes averaging;
- a preprocessing approach on the data channels that includes spike removal;
- a power spectral density feature from the data channels that is used to skip inappropriate estimated heart rate;
- 10 a zero crossing feature from the data channels that is used to skip inappropriate estimated heart rate;
- the ability to select the lowest noise signal from the two or more selected data channels;
- the ability to remove the signal from the common mode noise of the two or more data channels selected;
- 15 the ability to remove the noise from the first channel and all other channels using the second channel of data with the signal removed;
- using the first channel or least noisy of the other channels to estimate heart rate;
- comparing the new heart rate with the previous heart rate and extracted zero crossing and power spectral density features; and
- 20 updating the heart rate and return to acquiring a new set of channels of data.

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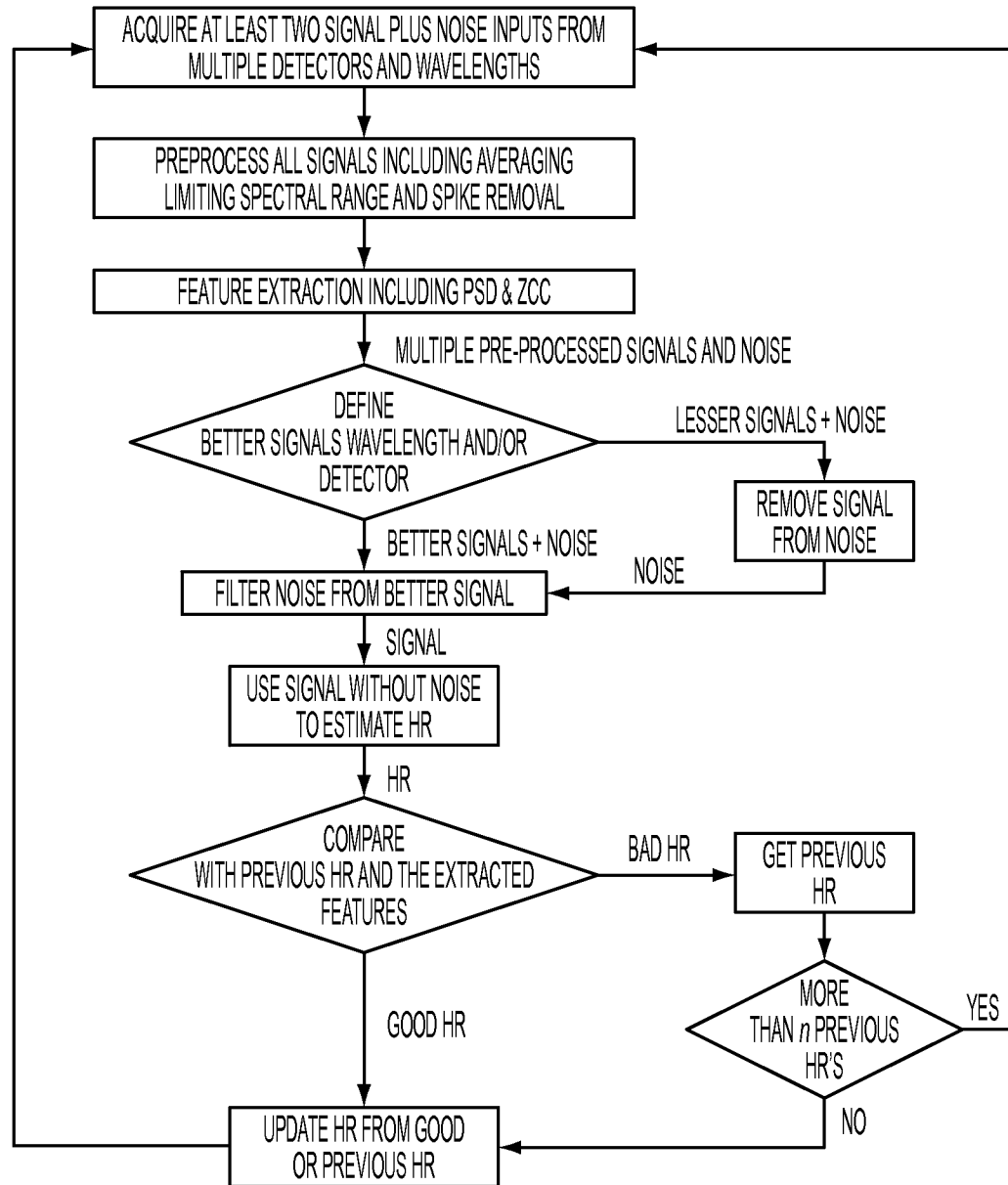


FIG. 1

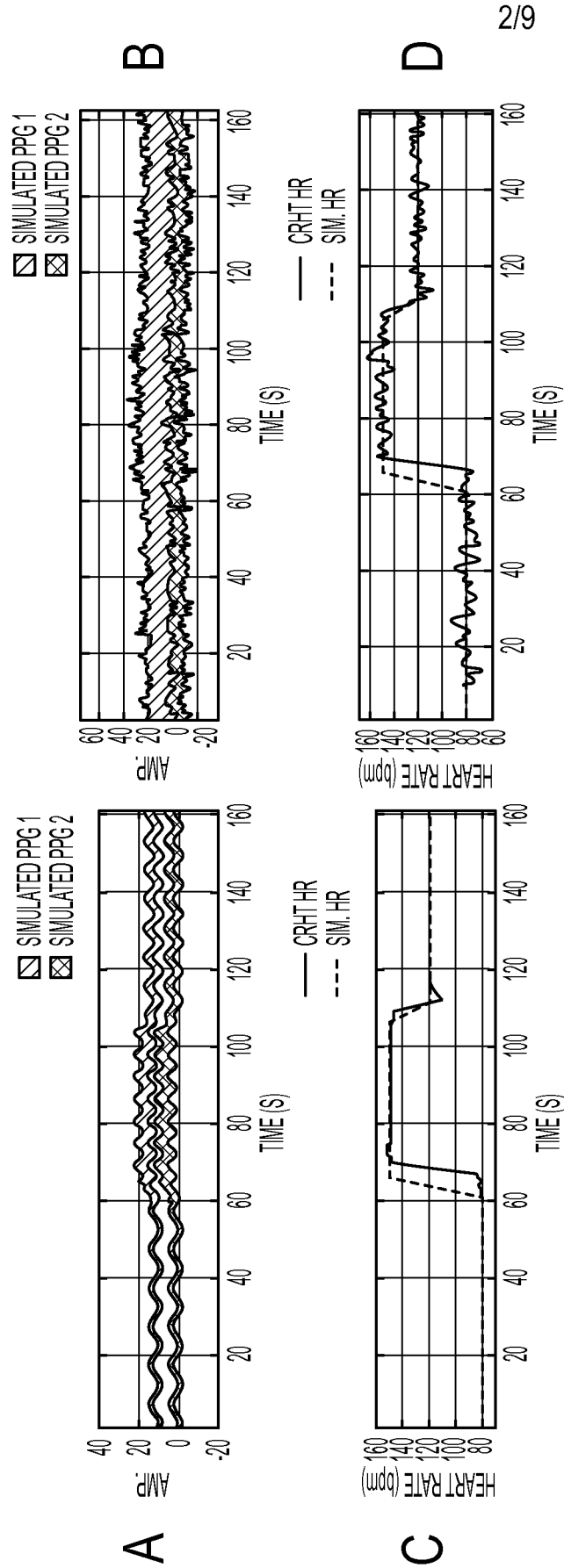


FIG. 2

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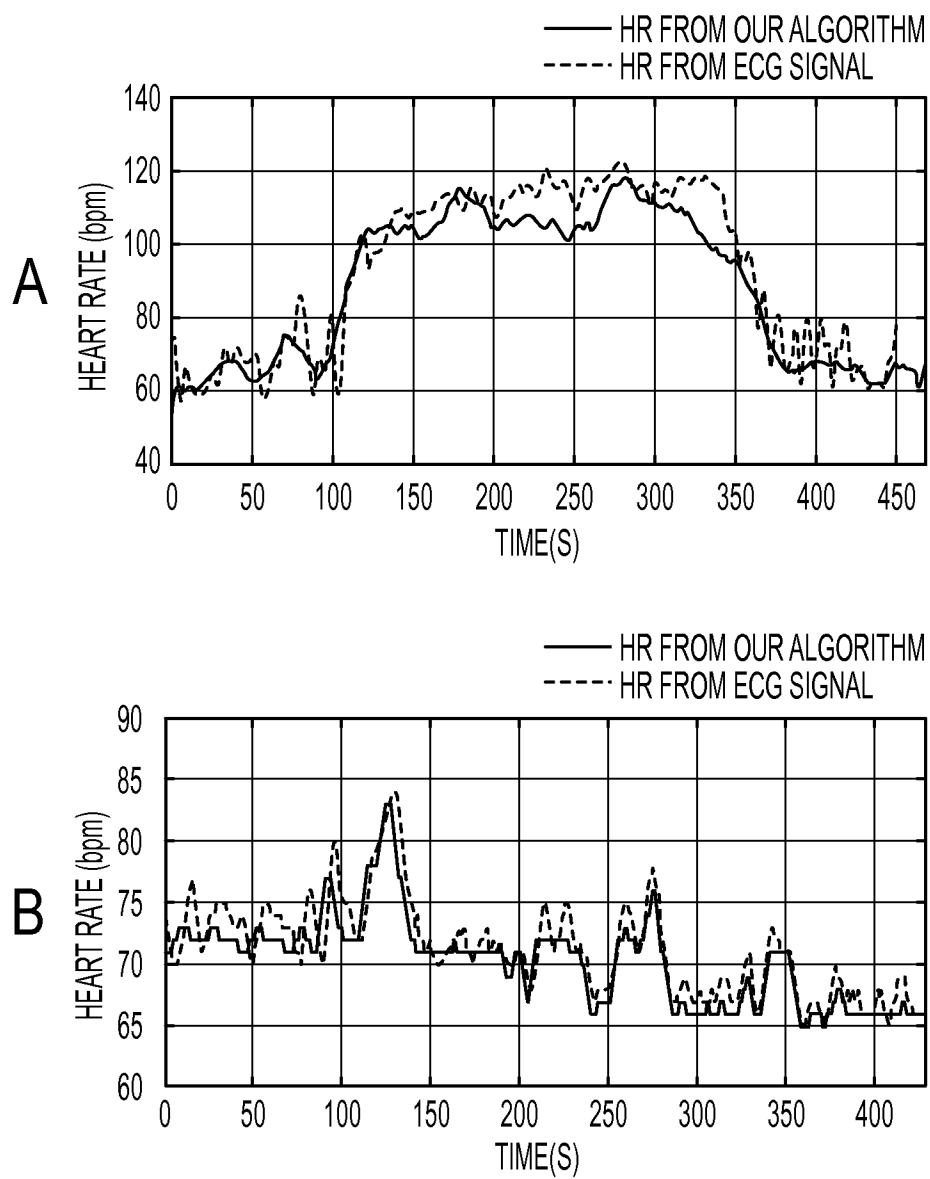


FIG. 3

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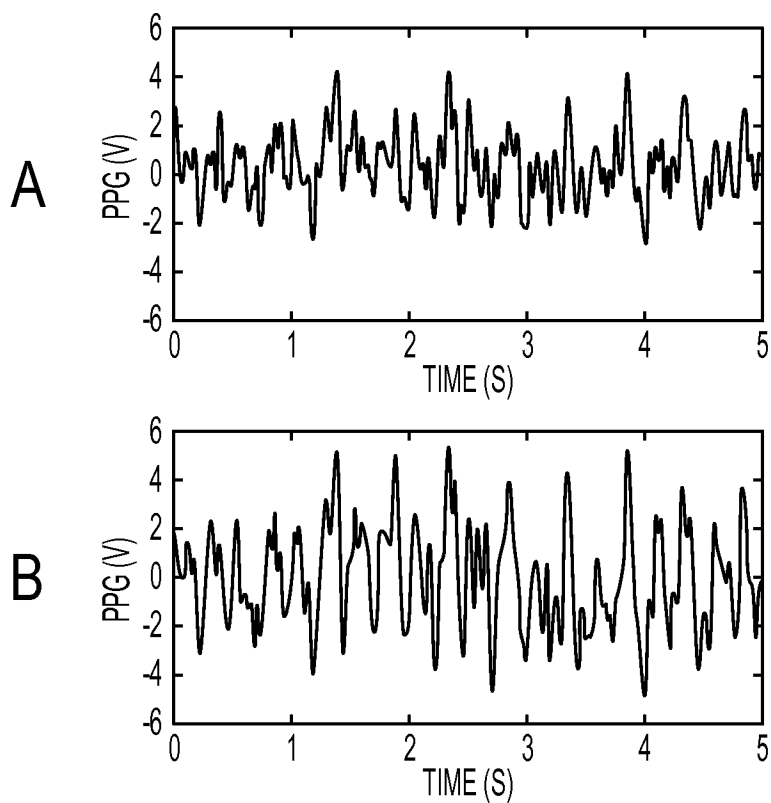


FIG. 4

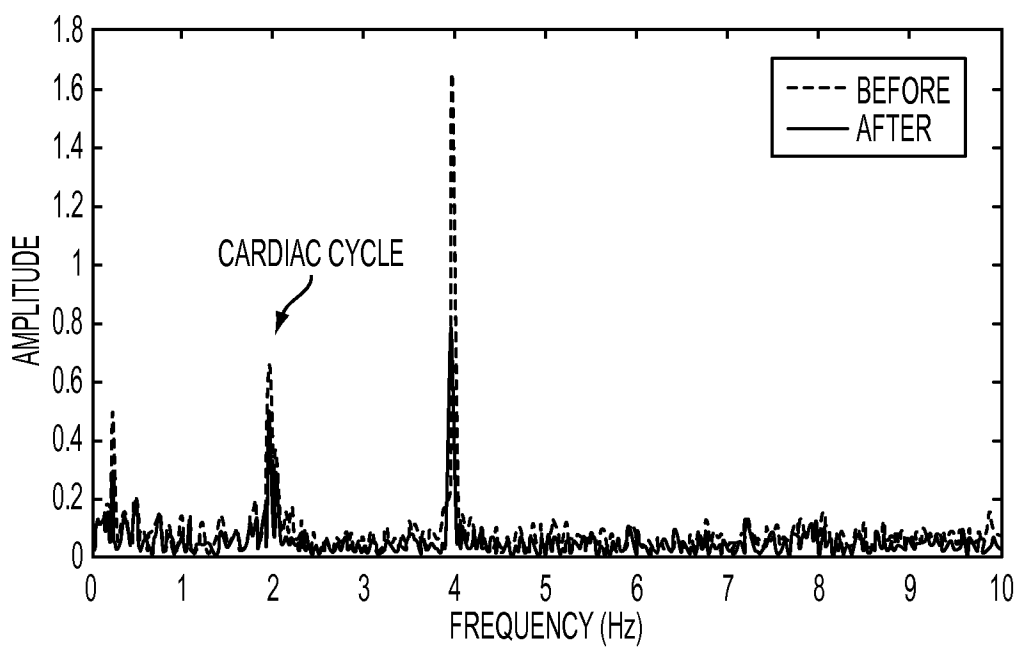


FIG. 5

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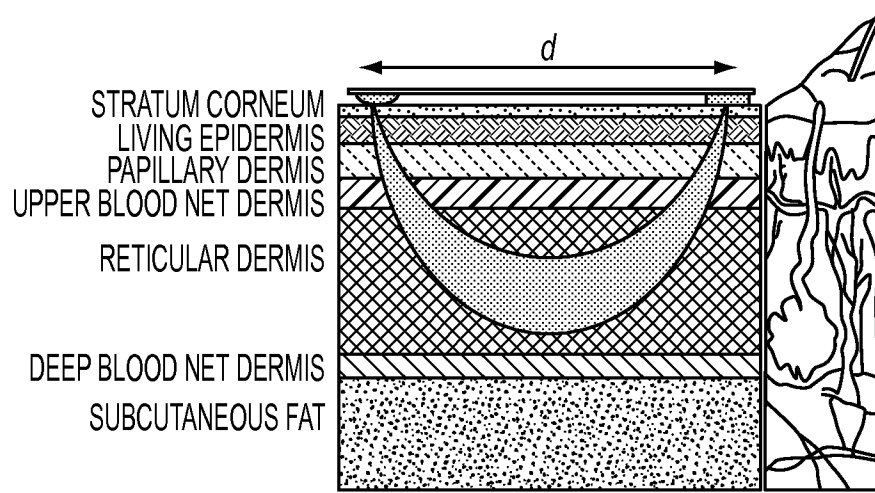


FIG. 6

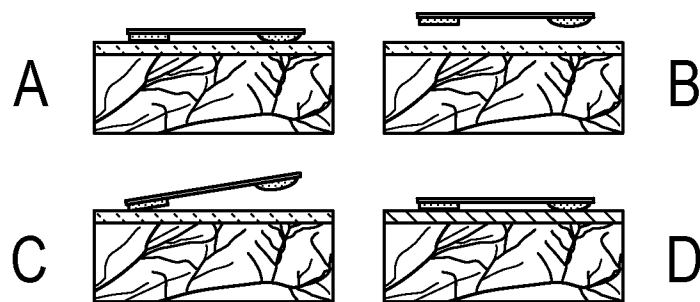


FIG. 7

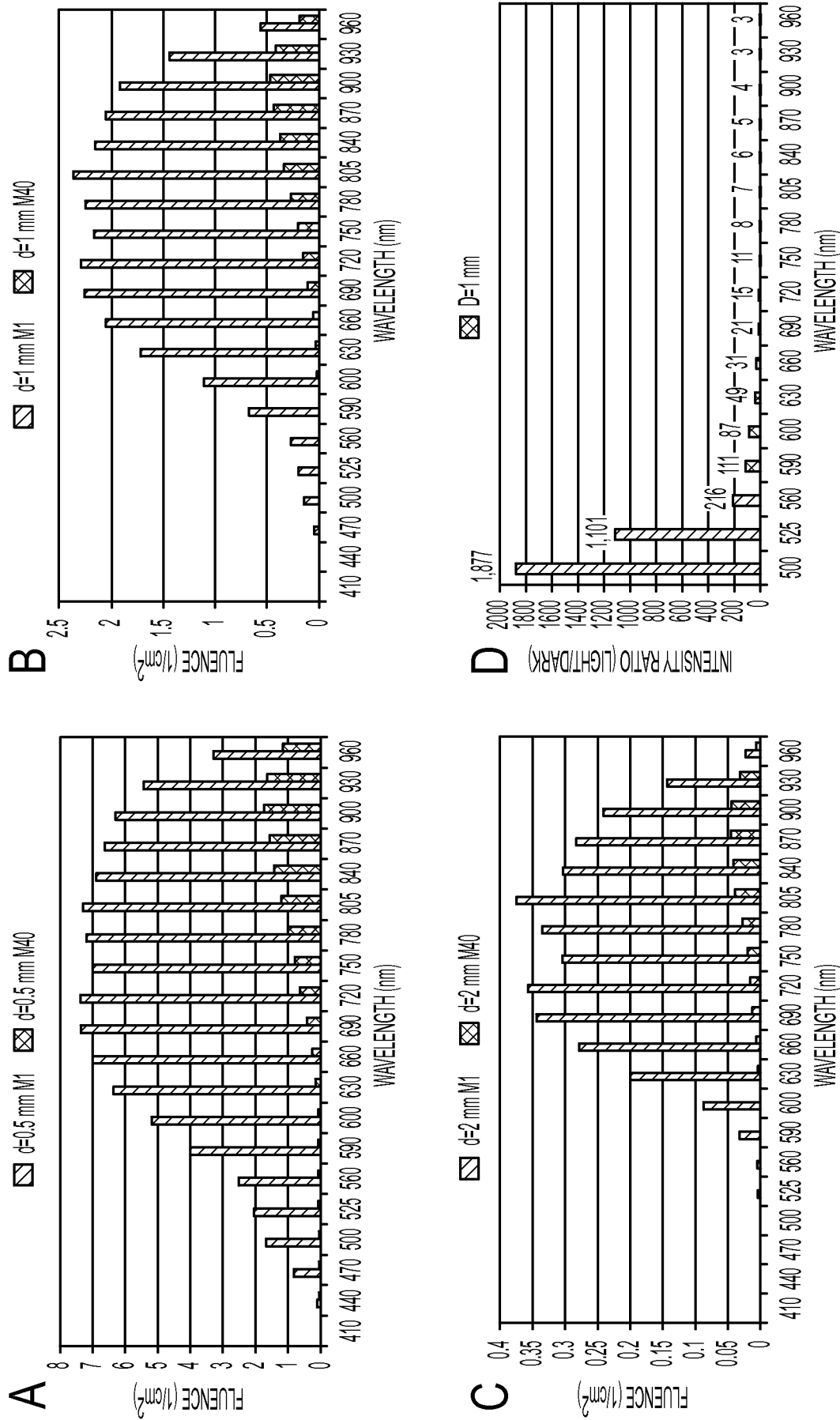


FIG. 8

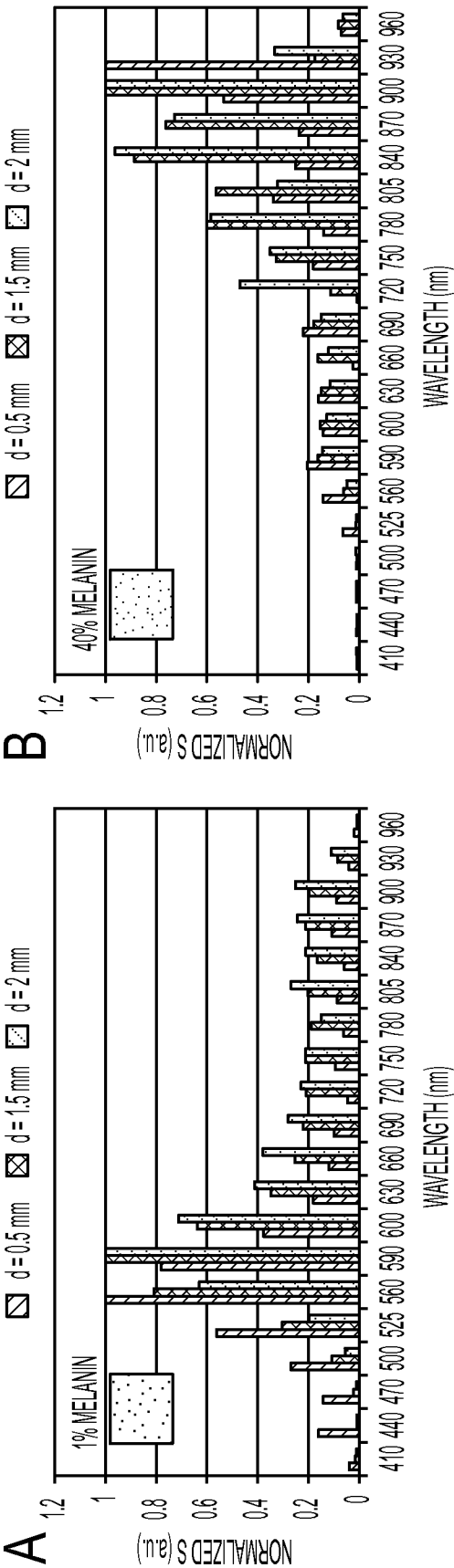


FIG. 9

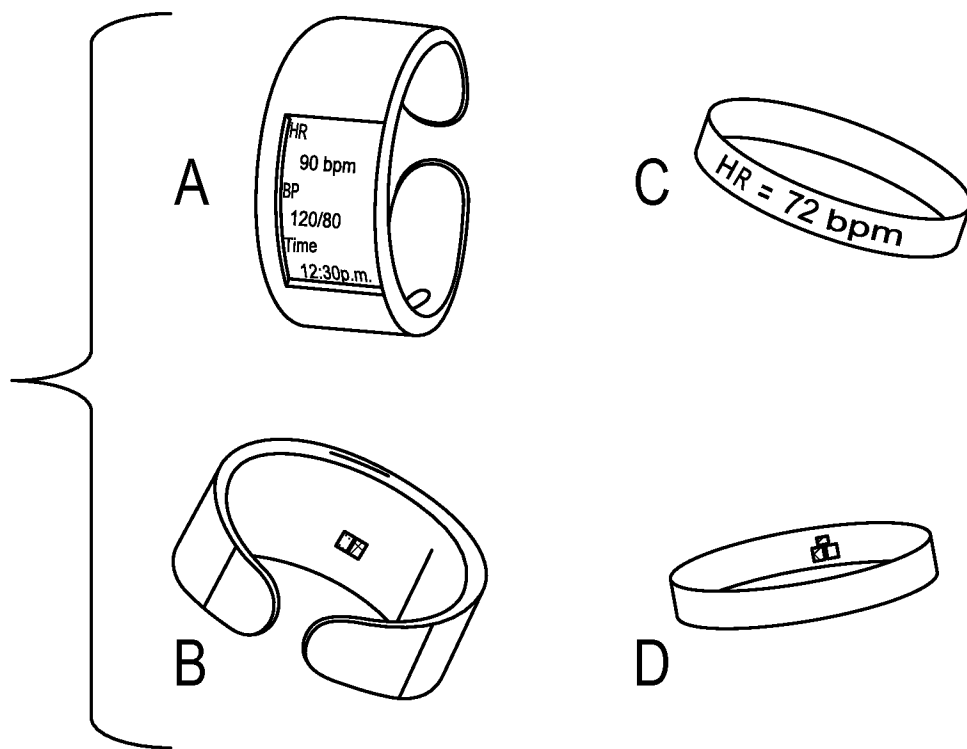


FIG. 10

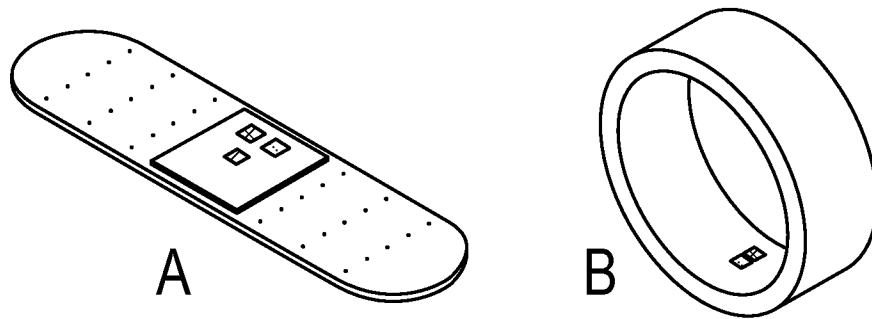


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2015/033834

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 5/02 (2015.01)

CPC - A61B 5/02 (2015.04)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) -A61B 5/00, A61B 5/01, A61B 5/02, A61B 5/024, A61B 5/145, A61B 5/1455 (2015.01)

USPC -600/301, 600/473, 600/476, 702/19

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

CPC -A61B 5/00, A61B 5/0002, A61B 5/0059, A61B 5/01, A61B 5/02, A61B 5/145, A61B 5/1455, A61B 5/72 (2015.04) (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Orbit, Google Patents, Google

Search terms used: sensor, wavelength, channels, power spectral density, zero crossing, wearable monitor

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/0107493 A1 (FITBIT INC) 17 April 2014 (17.04.2014) entire document	1-24
Y		25
Y	US 7,336,982 B2 (YOO) 26 February 2008 (26.02.2008) entire document	25
Y	US 5,954,644 A (DETLING et al) 21 September 1999 (21.09.1999) entire document	25
Y	US 8,562,526 B2 (HENEGHAN et al) 22 October 2013 (22.10.2013) entire document	25

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

31 July 2015

Date of mailing of the international search report

14 AUG 2015

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