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(71) **Applicant: THE ACCESS TECHNOLOGIES** [CA/CA]; 28 Northside Road, Ottawa, Ontario K2H 5Z3 (CA).

(72) **Inventors: AHMAD, Saif**; 3 Eagleview Street, Kanata, Ontario K2M 2L6 (CA). **GARG, Atul K.**; 1360 Nadia Lane, Kanata, Ontario K2W 1A5 (CA).

(74) **Agent: MACRAE & CO.**; 326 Somerset St. West, Ottawa, Ontario K2P 0J9 (CA).

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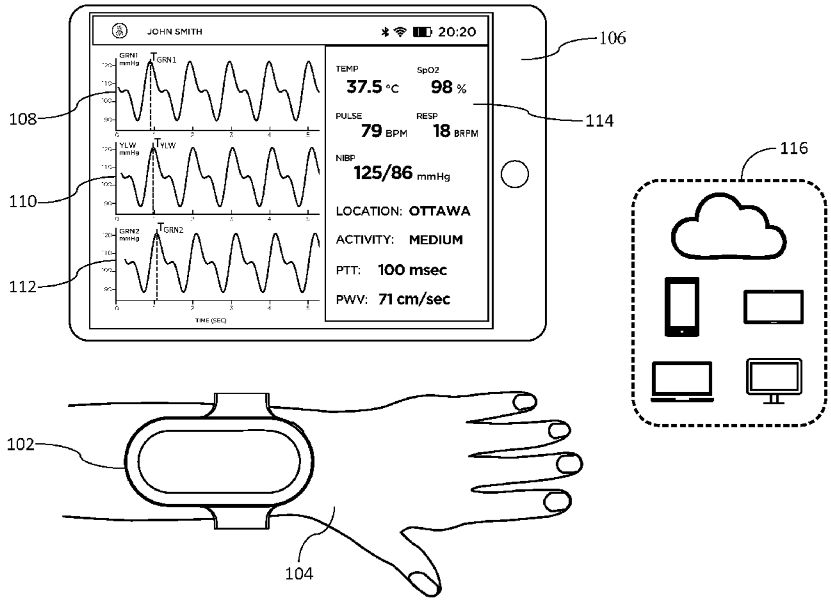

FIG. 1

(57) **Abstract:** An ergonomically designed smart wristband for clinical-grade multiparameter monitoring is disclosed. The smart wristband incorporates multiple sensors including custom-designed reflective arterial pulse sensors, a thermopile sensor, and electrocardiogram (ECG) electrodes. When the smart wristband is worn on the wrist, the biosensors contact the skin. The smart wristband may tether wirelessly to a mobile or any other computing device to continuously acquire and stream information like arterial pulse waveform and temperature data. Algorithms running on the computing device or onboard microprocessor analyze the acquired data to report parameters like blood pressure, body temperature, respiration, and blood oxygen. The device can also operate in a fully-standalone mode to accomplish continuous multiparameter physiological monitoring, analysis, and reporting. Whenever the user touches an electrode on the device with a finger of the other hand, an ECG signal is additionally acquired for monitoring parameters such as heart rate and

[Continued on next page]

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heart rate variability.

A SMART WRISTBAND FOR MULTIPARAMETER PHYSIOLOGICAL MONITORING

CROSS REFERENCE TO RELATED APPLICATIONS

The present application claims the priority benefit under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Serial No. 62/986,199, titled, "A SMART WRISTBAND FOR CONTINUOUS MULTIPARAMETER PHYSIOLOGICAL MONITORING," filed March 06, 2020, the disclosure of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

In general, the present invention relates to multiparameter monitoring in humans with wearable technology, and in particular to non-invasive blood pressure (NIBP), blood oxygen saturation (SpO_2), heart rate (HR), HR variability (HRV), respiration rate (RR), temperature, arterial pulse, and electrocardiogram (ECG) monitoring utilizing an ergonomically designed smart wristband.

BACKGROUND

The very first wrist wearable device is the mechanical movement timekeeping wristwatch that was developed in the early 19th century.

With rapid advancements in semiconductor and computing technologies, wristwatch technology has witnessed a massive growth whereby timekeeping has been accurately and efficiently accomplished via microcontrollers, digital crystals, and electronic displays. Moreover, modern day wristwatches have become increasingly smart and multifunctional such that in addition to timekeeping, they can easily perform tasks like browsing the Internet, making a telephone call, and playing audio/video media.

More recently, smartwatches or smart wristbands have been employed for non-invasively monitoring a variety of physiological phenomena and physical activity that enables users to keep track of their health. These devices are generally provided with biosensors that contact the skin of the user when worn around the wrist. In conjunction with an analog signal conditioning circuitry and a microcontroller, these biosensors acquire a variety of physiological data like arterial pulse waveform and electrocardiogram (ECG) signals, which are then analyzed to evaluate parameters like HR and blood oxygen saturation (SpO_2). User activity is generally monitored by analyzing the data collected by an accelerometer (ACL) provided in the device.

Smartwatches and health bands manufactured by companies like Apple, Fitbit, Samsung, Garmin, OshenWatch, and those disclosed in other prior art utilize the reflective photoplethysmography (PPG) technique to acquire arterial pulse waveform signals from the wrist. This technology generally comprises a photodiode (PD) or optical sensor along with closely located light emitting diodes (LEDs) that contact the skin of the wrist. When the LEDs glow, some light from the LEDs is absorbed by the skin while the remainder is reflected back. The PD picks up the reflected light that changes its intensity based on the changes in blood volume inside capillaries caused by the pumping of the blood by the heart. The signal picked up by the PD is conditioned and amplified using analog circuitry to characterize the arterial pulse waveform signal. The arterial pulse wave signal is then digitized via an analog to digital converter (ADC) by the microcontroller. Quite often, LEDs of different colors (or wavelengths) are utilized within the reflective PPG methodology to acquire multiple pulse waveform signals – such that each pulse waveform signal corresponds to a specific LED color or wavelength. The acquired arterial pulse waveform signals are analyzed to evaluate and monitor parameters like HR, SpO_2, and NIBP.

Moreover, smartwatches and health bands manufactured by companies such as Apple, Fitbit, Samsung, and those disclosed in other prior art often have the functionality to acquire an ECG signal from the wrist. To this end, a set of dry electrodes are provided on the backplate of the smartwatch while another set of dry electrodes are provided on the smartwatch face. When the user wears the smartwatch on one wrist, the backplate electrodes contact the skin of the wrist. The user then touches the smartwatch face electrodes with a finger of the other hand. This completes the ECG circuit and configures the electrodes to measure the biopotential difference between the left and right side of the body. Internally, these electrodes are connected to a differential amplifier that amplifies and conditions this biopotential difference to characterize the ECG signal. The ECG signal is then digitized via an ADC by the microcontroller. The acquired ECG signal is analyzed to evaluate and monitor parameters like HR and HRV.

Based on the ongoing discussion, it is evident that non-invasive wrist-worn physiological monitors offer the most natural, convenient, and unobtrusive method for monitoring health. However, despite all the advancements described above, wrist-worn physiological monitoring technology still seems to suffer from two major problems. These two problems are briefly described below.

The first problem is the inability of non-invasive wrist-worn monitoring technology to achieve clinical-grade accuracy and consistency for assessing various physiological parameters, especially, SpO_2 and NIBP. The main reason for this problem is perhaps the complex wrist physiology whereby arteries and capillaries are embedded deep inside a bony anatomical structure which hinders clean arterial pulse waveform data acquisition via the reflective PPG methodology. When acquired pulse waveform data is low-fidelity and noisy, accurate estimation of parameters like SpO_2 and NIBP from this data becomes problematic.

The second problem is the failure of non-invasive wrist-worn monitoring technology to conveniently and seamlessly integrate multiparameter physiological monitoring. For example, at least 6 vital signs including HR, HRV, SpO_2, NIBP, RR, and body temperature are of paramount importance for not only assessing overall health but also for assessing various conditions like hypertension, chronic obstructive pulmonary disease (COPD), atrial fibrillation (AF), sleep apnea, heart failure (HF), and febrile events. Yet, none of the existing technologies seem to offer accurate measurement of all these parameters in a single wrist-worn device. The main reason for this problem is perhaps the fact that wrist-worn multiparameter monitoring technology is still undergoing development whereby further advancements and enhancements are forthcoming.

Therefore, the field of non-invasive wrist-worn clinical-grade multiparameter monitoring offers several opportunities for the development of ground-breaking technologies that promise to usher in a paradigm shift in the manner in which health is monitored.

SUMMARY

The present invention is directed towards non-invasive clinical-grade multiparameter monitoring.

In one example embodiment, there is provided a non-invasive, unobtrusive, sleek, single-piece, geometric stadium-shaped wearable smart wristband related to clinical-grade continuous multiparameter physiological monitoring. The smart wristband in one example is a sealed, waterproof, and dustproof unit made from materials like thermoplastic polymers. Moreover, straps made from an elastomeric material can be provided on the device for attachment to the wrist. The smart wristband may be equipped with a microcontroller with Wi-Fi and/or Bluetooth capabilities and may utilize a rechargeable battery for power. Moreover, the smart wristband may also be provided with a 3-axes ACL that is interfaced with the microcontroller via the inter-integrated circuit (I2C) bus.

In a further example embodiment, the smart wristband backplate is provided with three custom-designed reflective PPG arterial pulse sensors. Each reflective PPG arterial pulse sensor can comprise one PD surrounded by three LEDs. The three reflective PPG arterial pulse sensors may be spread along the length of the stadium-shaped backplate which in one embodiment could be approximately 3.0” long. Each of the three custom-designed reflective PPG arterial pulse sensors can be interfaced with an analog signal conditioning and amplification circuit. Output from each of the three analog signal conditioning and amplification circuits can be connected to a separate ADC channel of the microcontroller.

Additionally, in an example embodiment, the device backplate is provided with a thermopile temperature sensor in between two of the three reflective PPG arterial pulse sensors. The thermopile temperature sensor may be interfaced with the device microcontroller via the I2C bus.

When the smart wristband is worn on the wrist, in one aspect, the length of stadium-shaped device aligns with the forearm, and the PPG and thermopile sensors contact the skin of the wrist. With this configuration, the smart wristband acquires 3-channel arterial pulse waveform data, temperature data, and ACL data, and utilizes the Wi-Fi or Bluetooth protocol to wirelessly stream this data in real-time to a mobile device (for example, smartphone, tablet, etc.) and/or a computer (for example, laptop, desktop computer, etc.) running associated software to make this data transfer possible. Additional associated software running on the mobile device and/or computer may be configured to enable the smart wristband to leverage their respective displays to enable visualization of all incoming data. Specialized algorithms, applications, and software running on the mobile device and/or the computer are capable of analyzing the incoming data to evaluate and report various parameters including cuff-less NIBP, SpO_2, HR, RR, temperature, and user activity. Additionally, the algorithms, applications, and software running on the mobile device and/or the computer may utilize the global positioning system (GPS) capabilities of these devices to detect and report user location. Associated software running on the mobile device and/or the computer can enable storage of all information locally and/or utilize the Wi-Fi, Bluetooth, or other protocols to transfer and store this information in the cloud and/or on other external devices. All stored information can then be transferred from one point to another, utilizing the Internet or other communication protocols, thus making remote multiparameter physiological monitoring possible.

In another embodiment, the smart wristband is designed to be fully standalone whereby it is additionally equipped with a touchscreen display on its top face, an internal memory, and a GPS module. Moreover, the fully standalone smart wristband can be provided with two ECG electrodes on its backplate and a third ECG electrode on its top face that may be interfaced with an analog differential signal amplification and conditioning circuity. The output from the analog differential signal amplification and conditioning circuitry is capable of connecting to the fourth ADC channel of the microcontroller. When the smart wristband is worn on the wrist, the PPG sensors, the backplate ECG electrodes, and the thermopile sensor contact the skin of the wrist.

Additionally, the user touches the ECG electrode on the top face of the device with a finger of other hand. With this configuration, the fully standalone smart wristband acquires 3-channel arterial pulse waveform data, single channel ECG waveform data, temperature data, ACL data, and GPS data. Associated software running on the microcontroller can be configured to enable the touchscreen display to show incoming data in real-time. Moreover, algorithms and software running on the microcontroller are capable of processing incoming data to evaluate parameters including NIBP, SpO_2, HR, HRV, RR, temperature, user activity, and user location, and various results may be presented on the touchscreen display. Other information can also be presented on the screen. The fully standalone version of the smart wristband has the functionality to store all information locally in its internal memory. Moreover, the device is configured to optionally utilize the Wi-Fi, Bluetooth, or other protocols to transfer or stream information directly or from its internal memory to the cloud and/or to other external devices. Therefore, as described above, this functionality facilitates seamless remote multiparameter physiological monitoring.

In relation to the fully standalone smart wristband, it will be obvious to those skilled in the art that in case the user does not touch and hold the electrode provided on the device top face with a finger of the other hand, no ECG data will be acquired. In that case the device will only acquire and process 3-channel arterial pulse waveform data, temperature data, ACL data, and GPS data, and report associated parameters.

In one example, the smart wristband supports both manual and continuous monitoring. In manual monitoring, the user initiates a measurement that lasts a time period, such as 30 seconds, after which all data is analyzed, and results are reported. In continuous monitoring, the device automatically initiates a time period, such as a 30-second-long measurement every 15 minutes, analyzes data, and reports associated results. Again, it will be obvious to those skilled in the art that the duration of the measurements and their frequency can be easily modified as per desired monitoring needs.

In a further example embodiment, the arrangement of the three reflective PPG arterial pulse sensors along the length of the backplate of the smart wristband allows measurement of an important NIBP-related parameter called pulse transit time (PTT) between the three arterial pulse waveform signals. Since the distances between the three reflective PPG arterial pulse sensors are also known, another NIBP-related parameter called pulse wave velocity (PWV) can also be easily computed. Moreover, the amplitude of each of the three arterial pulse waveform signals is also related to the NIBP. In one example, the device is calibrated or trained by building correlations between three PTT and three pulse amplitude metrics, and NIBP measured by a standard device. Once calibrated or trained, the correlation model can be used to independently evaluate and report NIBP with clinical-grade accuracy. Preprocessing of the data from the biosensors can be undertaken using various digital signal processing (DSP) techniques such as resampling and digital filtering for removing unwanted noise and preparing the data for further analyses. This cam be followed by undertaking comprehensive data analysis utilizing specialized algorithms and software. The biosensors acquire a variety of physiological data such as arterial pulse waveform, electrocardiogram (ECG) signals, HR, HRV, SpO_2, NIBP, RR, body temperature, and user activity data.

In one embodiment of the smart wristband, the colors of the LEDs used in the three reflective PPG arterial pulse sensors are green (GRN1), yellow (YLW), and green (GRN2) respectively. With this configuration, utilizing different wavelengths of green (~517 nm) and yellow (~590 nm) light and their different absorption and reflection intensities by oxygenated and deoxygenated blood, two SpO_2 values (i. GRN1/YLW SpO_2 and ii. GRN2/YLW SpO_2) may be computed. The two computed SpO_2 values may be combined or fused using techniques such as arithmetic mean and weighted geometric mean to evaluate and report SpO_2 with clinical-grade accuracy.

In another embodiment of the smart wristband, the colors of the LEDs used in the three reflective PPG arterial pulse sensors are red (~660 nm), IR (~940 nm), and green (~517 nm) respectively. With this configuration, three SpO_2 values (i. red/IR SpO_2, ii. green/red SpO_2, and iii. green/IR SpO_2) may be computed as described above. Again, the computed SpO_2 values may be combined or fused using various techniques to evaluate and report SpO_2 with clinical-grade accuracy.

In a further aspect of the smart wristband, a HR value is calculated for each of the three arterial pulse waveform signals, resulting in three HR measurements per recording. These computed HR measurements may be combined using methods such as weighted mean to evaluate and report HR with clinical-grade accuracy. In another example, HRV information from the three arterial pulse wave signals and the ECG signal may be fused to evaluate and report HRV with clinical-grade accuracy.

In one example of the multiparameter smart wristband, respiratory sinus arrythmia (RSA) induced modulations in the three arterial pulse amplitudes, three arterial peak-to-peak intervals (PPIs), and three arterial PTTs may be utilized to estimate nine RRs, which may be followed by fusion of all calculated RRs to report RR with clinical-grade accuracy.

An arterial pulse originates at the heart and then travels to the periphery of the limbs. The described multiparameter smart wristband detects pulse arrival at three distinct locations along the wrist to measure three arterial pulses and three arterial PTTs. If the device is attached on the wrist in the correct direction, the estimated PTTs will be positive, and all related parameters will be computed accurately. However, if the device is attached on the wrist in the wrong direction, that is, it is rotated by 180 degrees, the estimated PTTs will be negative, and the computation of related parameters will suffer. In one embodiment, to overcome this limitation, the smart wristband first checks the signs of the measured PTTs. If the PTTs are found to be positive, no action is taken, and the computations proceed normally. However, if PTTs are determined to be negative, a warning may be generated to inform the user to correct the direction of the attachment of the smart wristband. As an alternative to changing the placement of the wristband, any detected negative PTT values may be transformed to positive values prior to carrying out associated computations.

In one example of the multiparameter smart wristband, the LEDs in each of the three reflective PPG arterial pulse sensors are always on. This could potentially cause the LEDs to heat up and could also lead to the LEDs associated with one PD to cause interference in other PDs – leading to loss in signal quality. To mitigate this problem, in one example, the multiparameter smart wristband may control the LEDs associated with each of the three PDs via three pulse width modulation (PWM) signals generated by three digital input/output (DIO) channels of the microcontroller. The three ADC channels interfaced with the three PDs can then be programmed to read data from a PD only when the LEDs associated with that PD are on, as determined by the duty cycles of the three PWM signals.

In one example, to enhance and standardize arterial pulse waveform signal quality and fidelity over all users, the multiparameter smart wristband utilizes the automatic gain control (AGC) technique. Here, gain of each of the three arterial pulse amplifiers may be controlled via a digital potentiometer that is also connected to the microcontroller, for example via the I2C bus. For each of the three arterial pulse waveform signals read by an ADC channel, the microcontroller may compute a peak-to-peak amplitude and accordingly alter the associated potentiometer’s resistance via the I2C bus to change the corresponding amplifier’s gain such that the peak-to-peak amplitude always stays above a given value, for example, 2.0 V. In a further example, the AGC technique described above may also be applied to the ECG signal to enhance and standardize its quality and fidelity over all users.

In one embodiment, the multiparameter smart wristband generates various health alerts based on the measured parameters and user activity level as determined by the ACL. For example, if the ACL data shows the subject at rest and the HR value is above 100 beats per minute (BPM), a tachycardia alert may be generated. Similarly, if the subject is resting and the NIBP value is above 140/90 mmHg, a hypertension alert may be generated.

Though this invention is described as related to a wearable multiparameter smart wristband that can be attached to a user’s left or right wrist, the underlying design and principle of the invention can be extended to a wearable device that can be attached and used at any location along any of the two upper or even the two lower limbs for physiological monitoring. One example comprises the smart wristband worn and used on the left wrist. Another example comprises the device worn and used on upper the right arm. Yet another example comprises the smart wristband worn and used on the left ankle. It will be appreciated that the multiparameter smart wristband could be a smartwatch or any other similar wearable.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates the multiparameter smart wristband worn by a user on the left hand and tethered wirelessly to a tablet for monitoring data along with other external devices to which monitored data is transferred.

FIGS. **2A-2B** illustrate the multiparameter smart wristband with its top face, power button, and backplate that incorporates reflective PPG arterial pulse sensors and thermopile sensor.

FIG. **3** illustrates an exploded view of the multiparameter smart wristband showing various components.

FIG. **4** illustrates an operational diagram of the multiparameter smart wristband showing several components and their various connections.

FIG. **5** illustrates a fully standalone version of the multiparameter smart wristband worn by a user on the left hand for monitoring data along with other external devices to which monitored data is wirelessly transferred.

FIG. **6** illustrates a fully standalone version of the multiparameter smart wristband worn by a user on the left hand with the index finger of the right hand touching the top face ECG electrode for monitoring data that includes ECG data along with other external devices to which monitored data is wirelessly transferred.

FIGS. **7A-7B** illustrate a fully standalone version of the multiparameter smart wristband with its top face, power button, and backplate that incorporates reflective PPG arterial pulse sensors, thermopile sensor, and ECG electrodes.

FIG. **8** illustrates an exploded view of the fully standalone version of the multiparameter smart wristband showing various components.

FIG. **9** illustrates an operational diagram of the fully standalone version of the multiparameter smart wristband showing several components and their various connections.

FIGS. **10A-10B** illustrate that when the multiparameter smart wristband is attached to the wrist in the correct direction, PTT values are positive.

FIGS. **11A-11B** illustrate that when the multiparameter smart wristband is attached to the wrist in the incorrect direction, PTT values are negative.

FIG. **12** illustrates the PWM technique that is utilized inside the multiparameter smart wristband for switching LEDs associated with the three PD sensors and synchronously reading data from these PD sensors.

FIG. **13** illustrates an operational diagram of the AGC scheme that is utilized inside the multiparameter smart wristband to standardize arterial pulse waveform signal quality and fidelity over all users.

FIG. **14** illustrates an operational diagram of the AGC scheme that is utilized inside the multiparameter smart wristband to standardize ECG signal quality and fidelity over all users.

FIG. **15** illustrates a flowchart depicting the method of manual and continuous monitoring accomplished by the multiparameter smart wristband.

FIG. **16** illustrates a flowchart depicting the generation of various health alerts by the multiparameter smart wristband.

FIG. **17** illustrates examples of various locations on the human body where wearables employing the underlying design and principle of the multiparameter smart wristband can be attached to undertake monitoring.

FIGS. **18A-18B** illustrate the multiparameter smart wristband and the fully standalone version of the multiparameter smart wristband being charged on two different kinds of wireless charging units.

DETAILED DESCRIPTION

A preferred embodiment of the present invention will be set forth in detail with reference to the drawings, in which like reference numerals refer to like elements or method steps throughout.

FIG. **1** illustrates one embodiment of the multiparameter smart wristband worn by a user on the left hand and tethered wirelessly to a tablet for monitoring data along with other external devices to which monitored data is transferred. In this example, the smart wristband **102** is worn by the user on the left hand **104** resulting in the contact of the biosensors on the device backplate (not shown) with the skin of the wrist. The smart wristband **102** runs embedded software and communicates wirelessly with a tablet **106** running a dedicated application to accomplish real-time data acquisition and streaming to the tablet **106** via protocols such as Wi-Fi and Bluetooth. The data transferred by the smart wristband **102** to the tablet **106** includes 3-channel arterial pulse waveform signals **108**, **110**, **112** acquired and streamed at a sampling rate of 100 Hz each utilizing three reflective PPG arterial pulse sensors (not shown) provided on the backplate of the smart wristband **102**, ACL data acquired and streamed at a sampling rate of 10 Hz utilizing an ACL sensor (not shown) provided inside the smart wristband **102**, and temperature data acquired and streamed at a sampling rate of 1.0 Hz utilizing a thermopile sensor (not shown) provided on the backplate of the smart wristband **102**. The dedicated application running on the tablet **106** simultaneously acquires GPS data at a sampling rate of 1.0 Hz utilizing the GPS capabilities of the tablet **106**. In this example, all acquired data is analyzed by the dedicated application running on the tablet **106** to report parameters such as NIBP, SpO_2, HR, RR, temperature, location, activity, PTT, and PVW **114**. In this embodiment of the smart wristband, the dedicated application running on the tablet **106** is capable of transferring all monitored data to other external devices **116,** such as the cloud, smartphones, and computers, thus enabling seamless remote physiological monitoring. It will be obvious to those skilled in the art that the tablet **106** can be easily replaced by other similar computing devices such as a smartphone, a laptop, and a desktop computer without affecting the overall functionality of the exemplary monitoring system. Moreover, the data sampling frequencies mentioned in the description represent only one example and can be changed as per desired monitoring requirements.

FIGS. **2A-2B** illustrate an example of the multiparameter smart wristband with its top face, power button, and backplate that incorporates reflective PPG arterial pulse sensors and a thermopile sensor. In this embodiment, the smart wristband **102** comprises a flat top face **202** with no display. A power button **204** is utilized to switch the smart wristband **102** on and off. When the power button **204** is used to switch the smart wristband **102** on, an LED provided inside the device (not shown) turns on, the light from which is transmitted to the device's top face **202** via a light pipe (not shown) to indicate that the device is on. The backplate **206** is provided with three reflective PPG arterial pulse sensors. The first PPG arterial pulse sensor comprises a PD **208** surrounded by three LEDs **210** of a given color. Moreover, the second PPG arterial pulse sensor comprises a PD **212** surrounded by three LEDs **214** of another color. Additionally, the third PPG arterial pulse sensor comprises a PD **216** surrounded by three LEDs **218** of yet another color. The backplate **206** is also provided with a thermopile temperature sensor **220** that is placed in between the second and third PPG arterial pulse sensors. The LEDs **222** on the backplate **206** indicate the charging status of the smart wristband **102**. The screws **224** are used to fasten together the backplate **206** and top face **202** of the smart wristband **102**.

One skilled in the art will appreciate that variants exist in the arrangement and configuration of the components on the backplate **206**. For example, the thermopile temperature sensor **220** may be located between the first and second PPG arterial pulse sensors. Similarly, two or more of the LED sets **210**, **214** and **218** could have the same colour.

In one example the smart wristband **102** is in the shape of a geometric stadium of overall length 3.45", overall width 1.60", and overall thickness 0.55". Moreover, the distance between: (i) PD **208** of the first PPG arterial pulse sensor and the PD **212** of the second PPG arterial pulse sensor is 0.98”, (ii) PD **212** of the second PPG arterial pulse sensor and the PD **216** of the third PPG arterial pulse sensor is 1.64”, and (iii) PD **208** of the first PPG arterial pulse sensor and the PD **216** of the third PPG arterial pulse sensor is 2.62”. Therefore, when the smart wristband **102** is worn on the wrist as shown in FIG. **1**, the PPG arterial pulse sensors described above measure three arterial pulse waveform signals at three distinct locations along the wrist separated by distances of 0.98”, 1.64”, and 2.62”. Since the arterial pulse wave travels from the heart to the periphery of the limbs, the above arrangement of PPG arterial pulse sensors enable acquisition of three arterial pulses with three different pulse arrival times. These different pulse arrival times enable the computation of three PTT metrics. Moreover, since the distances between each of the three PDs are known, the computation of three corresponding PWV metrics is straightforward.

One skilled in the art will appreciate that variants exist in the sizing of the smart wristband and location of the three PPG arterial pulse sensor. It is only necessary for the three separate PPG arterial pulse sensors to be spaced apart in a manner to detect three separate arterial pulses; accordingly, the exact location of the PPG arterial pulse sensors within the backplate **206** can vary. Similarly, the size and shape of the smart wristband **102** can vary. For example, while an oblong or oval shape of a geometric stadium is preferred, one skilled in the art could configure the shape as rectangular, circular or any other shape that would accommodate three separate PPG arterial pulse sensors spaced apart in a manner to detect three separate arterial pulses.

FIG. **3** illustrates an exploded view of the example multiparameter smart wristband showing various components. In one example embodiment, the backplate **206** comprises a light barrier boundary **302** that prevents light crosstalk between various LEDs and PDs to enable acquisition of high-quality arterial pulse waveform data. In a further example embodiment, the backplate **206** is manufactured via the industrial co-moulding process whereby the backplate material is moulded using acrylonitrile butadiene styrene (ABS) while each of the window cut-outs for the PDs **208**, **212**, **216**, LEDs **210**, **214**, **218**, **222**, and thermopile sensor **220** is moulded using transparent acrylic. This process creates individualized transparent acrylic lenses that separately cover each LED, each PD, and the thermopile sensor. There are two advantages of the described co-moulding process. First, it fully encapsulates the LEDs **210**, **214**, **218**, **222**, PDs **208**, **212**, **216**, and the thermopile sensor **220** to efficiently provide waterproofing and dustproofing. Secondly and most importantly, it restricts any internal light spread within a lens to that lens only, again preventing light crosstalk between various LEDs and PDs to enable acquisition of high-fidelity arterial pulse waveform data. Other methods of manufacturing may also be used to manufacture the backplate **206**.

In the example embodiment shown in FIG. **3**, the PDs **208**, **212**, **216**, LEDs **210**, **214**, **218**, **222**, and thermopile sensor **220** are mounted (not shown) on a custom-designed printed circuit board (PCB) **304**. The power button **204** is also mounted on the PCB **304**. Other types of mountings can be contemplated by those skilled in the art.

Referring to FIG. **3**, in one embodiment, the device strap **312** may be made from elastomeric rubber. The strap **312** may be manufactured as a single piece wherein a gasket **318** is integrated with the strap **312**. The gasket portion **318** of the strap **312** helps to make the device waterproof and dustproof. The strap **312** may also be provided with a clasp **314** and holes **316** that enable the device to be conveniently fastened around the wrist to achieve a snug fit. Other arrangements of clasps, holes, and materials for formation of the device strap **312** may be used. For example, Velcro$^{\text{TM}}$ could be used for closure of the straps. In addition, while inclusion of the gasket **318** provides advantages, the gasket **318** is optional and the strap **312** may be manufactured without it. Furthermore, the strap may be formed of multiple pieces if required. While it is advantageous to manufacture the smart wristband as a sealed, waterproof, and dustproof unit, other configurations are envisioned that are not sealed, waterproof, and/or dustproof, depending upon the needs of the user. In addition, the strap could be formed of other material besides elastomeric rubber, such as nylon-like material or other suitable materials.

FIG. **3** also shows a rechargeable battery **306** provided inside the device. In one example, the device PCB **304** is provided with Qi wireless charging circuitry to which is attached a charging coil **308**. With this configuration, the device battery **306** is charged utilizing the Qi wireless charging protocol. The wireless charging circuitry integrated with the PCB **304** enables the device battery to be charged wirelessly with a standard wireless charger. This enables the device enclosure to be completely sealed, simplifying the waterproofing requirement. Other forms of power sources for the device can be contemplated, such as through removable and/or replaceable batteries or through wired charging.

With reference to FIG. **3**, an optional light pipe **310** is provided to carry light from the power on indication LED (not shown) provided on the PCB **304** to the top face **202** of the multiparameter smart wristband **102**. Finally, the screws **224** fasten all components together.

FIG. **4** illustrates an exemplary operational diagram of the multiparameter smart wristband showing several components and their various connections. The brightness of the three LED clusters **210**, **214**, **218** may be controlled via three resistors **402**, **404**, **406** respectively. The three PDs **208**, **212**, **216** are connected to three analog signal amplification and conditioning circuits **408**, **410**, **412** respectively, the outputs of which are connected to three ADC channels (ADC0, ADC1, ADC3) of the microcontroller **414**. The thermopile temperature sensor **220** may be connected to the microcontroller **414** via the I2C bus. Moreover, ACL sensor **416** may also be connected to the microcontroller **414** through the I2C bus. A radio transceiver **418** along with an antenna **420** may be connected to the microcontroller **414** that enables the smart wristband to communicate wirelessly with the outside world utilizing protocols such as Wi-Fi and Bluetooth.

Referring to FIG. **1**, FIG. **2B**, and FIG. **4**, in one embodiment, the LED cluster **210** comprises three green LEDs (D_4, D_5, D_6), the LED cluster **214** comprises three yellow LEDs (D_7, D_8, D_9), and the LED cluster **218** comprises three green LEDs (D_{10}, D_{11}, D_{12}). The three acquired pulse waveform signals can therefore be referred to as green 1 (GRN1) **108**, yellow (YLW) **110**, and green 2 (GRN2) **112** since these signals are collected by three PDs **208**, **212**, **216** that correspond to the green **210**, yellow **214**, and green **218** LED clusters. The pulse arrival time for each of the three pulse waveform signals **108**, **110**, **112** will be different. Therefore, it can be assumed that the time at which signal GRN1 **108** peaks is T_{GRN1}, the time at which signal YLW **110** peaks is T_{YLW}, and the time at which signal GRN2 **112** peaks is T_{GRN2}. The three PTTs can therefore be defined as follows:

$$PTT_{YG1} = T_{YLW} - T_{GRN1} \tag{1}$$

$$PTT_{G2Y} = T_{GRN2} - T_{YLW} \tag{2}$$

$$PTT_{G2G1} = T_{GRN2} - T_{GRN1} \tag{3}$$

Further, based on the distances between the three PDs **208**, **212**, **216** and equations (1) to (3) above, three PWVs can be defined as follows:

$$PWV_{YG1} = 0.98/PTT_{YG1} \tag{4}$$

$$PWV_{G2Y} = 1.64/PTT_{G2Y} \tag{5}$$

$$PWV_{G2G1} = 2.62/PTT_{G2G1} \tag{6}$$

Since the distances between the three PDs **208**, **212**, **216** are always fixed in the multiparameter smart wristband **102**, the resulting measurements of the PTT and PWV metrics will be standardized across all subjects. That is, any differences observed in these metrics across various subjects will be actual differences that arise due to subject physiology alone and not due to the measurement mechanism. For example, if PTT is measured using an ECG signal and an arterial pulse waveform signal measured at the index finger, the value of the measured PTT will be dependent on the physical distance between the heart (where the ECG signal originates) and the index finger (where the pulse waveform signal is measured). This physical distance will change for every subject based on characteristics like height and built. Therefore, the PTT measured via this method will not be standardized across all subjects and differences observed across subjects will also be a function of factors such as subject height and build. Moreover, to compute PWV, the above-mentioned physical distance will have to be measured or known, making the ECG-based method of PTT measurement cumbersome. On the other hand, the design of the multiparameter smart wristband **102** offers an extremely standardized and convenient method of measuring PTT and PWV.

Referring to FIG. **1**, the respective amplitudes of the GRN1 **108**, YLW **110**, and GRN2 **112** pulse waveforms can be represented by A_{G1}, A_{Y}, A_{G2}. Similarly, the respective PPIs can be represented by PPI_{G1}, PPI_{Y}, PPI_{G2}.

The PTT, PWV, and pulse amplitude information obtained from the three arterial pulse waveform signals **108**, **110**, and **112** can be combined using various statistical and computational techniques to evaluate NIBP. In one embodiment, the three PTT and the three pulse amplitude metrics are combined inside a multiple regression model to determine NIBP as follows:

$$NIBP = B_0 + B_1 * PTT_{YG1} + B_2 * PTT_{G2Y} + B_3 * PTT_{G2G1} + B_4 * A_{G1} + B5 * A_Y + B_6 * A_{G2} \tag{7}$$

The multiple regression model described in equation (7) is trained utilizing simultaneous measurements from the multiparameter smart wristband **102** and a standard NIBP device on various subjects to determine constants B_0-B_6. Once trained, the linear regression model of equation (7) may be used to evaluate and report cuff-less NIBP with clinical-grade accuracy.

In another embodiment, a log product of the three PWV and the three pulse amplitude metrics are combined inside a regression model to determine cuff-less NIBP with clinical-grade accuracy as follows:

$$NIBP = B_0 + B_1 * log\,(PWV_{YG1} * PWV_{G2Y} * PWV_{G2G1} * A_{G1} * A_Y * A_{G2}) \tag{8}$$

NIBP is generally reported as two numbers, namely, systolic pressure (SP) and diastolic pressure (DP), whereby the unit of measurement is mmHg. In equations (7) and (8), the NIBP term can be replaced by either SP or DP. Since SP is different in magnitude (generally 120 mmHg) than the DP (generally 80 mmHg), separate regression models (of the type shown in equations (7) and (8)) are built for SP and DP. Once calibrated, these models may be utilized to evaluate and report cuff-less SP and DP with clinical-grade accuracy.

Calibration and training may occur using a standard peripheral BP monitor on a per subject and population cohort basis. Relationship mappings between PWV and systolic/diastolic pressure may be created using various techniques like statistical linear/nonlinear regressions and artificial neural network modeling. An advantage is that the relationship mappings can also be created using an aortic/carotid BP monitor. Therefore, after calibration and training, peripheral and/or aortic/carotid BP can be reported using PTT/PWV information obtained from the acquired PPG pulse waveform data. The device may be calibrated and trained by creating relationship mappings between pulse peaks/troughs/amplitudes and standard peripheral and/or aortic/carotid BP devices.

The multiparameter smart wristband **102** may combine the three PPIs using various statistical and computational techniques to evaluate HR with clinical-grade accuracy. In one example, a non-weighted mean is used as follows:

$$HR = 60/[(PPI_{G1} + PPI_{Y} + PPI_{G2})/3] \tag{9}$$

Referring to equation (9), the unit of measurement of PPIs is seconds and division of 60 by the average of PPIs results in a HR reported in BPM.

In one example, the multiparameter smart wristband **102** may utilize the RSA induced modulations in the three arterial pulse amplitudes, three PPIs, and three PTTs to estimate nine RRs in breaths per minute (BRPM). This may be followed by fusion of all calculated RRs utilizing various mathematical and computational techniques to report RR with clinical-grade accuracy. Key steps of RR computation are: (i) peak detection, (ii) peak interpolation, (iii) bandpass filtering, (iv) peak detection & respiration rate extraction, and (v) fusion of all respiration rates. In one embodiment, the nine resulting RRs are aggregated by computing their weighted mean as follows:

$$RR = \frac{\sum_{i=0}^{n-1} W_{RRi} RR_i}{\sum_{i=0}^{n-1} W_{RRi}} \tag{10}$$

In equation (10), the weights are represented by W_{RRi} whereby the total number of RRs are $n = 9$. In this manner, aggregated RR may be evaluated and reported in BRPM with clinical-grade accuracy.

In one embodiment the smart wristband **102**, utilizes: (i) the ratio between GRN1 and YLW pulse waveform signals to evaluate a first SpO_2 value and (ii) the ratio between GRN2 and YLW pulse waveform signals to evaluate a second SpO_2 value. In another example, the multiparameter smart wristband **102** employs red, IR, and green LED clusters inside its three PPG arterial pulse sensors and utilizes: (i) the ratio between red and IR pulse waveform signals to evaluate a first SpO_2 value, (ii) the ratio between green and red pulse waveform signals to evaluate a second SpO_2 value, and (iii) the ratio between green and IR pulse waveform signals to evaluate a third SpO_2 value. The evaluated SpO_2 values are then fused utilizing various statistical techniques to report SpO_2 as a percentage with clinical-grade accuracy. The three SpO_2 values obtained from the red, IR, and green pulse waveform signals can be represented as S_{RIR}, S_{GR}, and S_{GIR}. In one example, the smart wristband **102**, may use an unweighted geometric mean to aggregate these three SpO_2 values as follows:

$$SpO_2 = \sqrt[3]{S_{RIR} * S_{GR} * S_{GIR}} \qquad (11)$$

With reference to FIG. **1** and FIGS. **2A-2B**, appropriate placement of the three custom-designed reflective PPG arterial pulse sensors along the backplate **206** of the smart wristband **102** facilitates the measurement of arterial pulses at three distinct locations **208**, **212**, **216** along the wrist, thus reducing positional dependency of pulse measurement on the wrist and increasing the probability of collection of good quality signals at one or more locations. For example, if the quality of the first arterial pulse waveform signal **108** in not good, there is a probability that the quality of the second arterial pulse waveform signal **110** is better, and so on. The fusion of information from all three pulse waveform signals **108**, **110**, **112** as described above thus results in the estimation of parameters such as HR, RR, SpO_2, and NIBP with clinical-grade accuracy.

FIG. **5** illustrates an example of a fully standalone version of the multiparameter smart wristband worn by a user on the left hand for monitoring data along with other external devices to which monitored data is optionally wirelessly transferred or streamed. In this example the multiparameter smart wristband **102** is fully standalone and is worn on the left hand **104**. The multiparameter smart wristband **102** comprises a touchscreen display **502** on its top face **202** for visualizing signals and results and giving inputs to the device. The device **102** may also be provided with two ECG electrodes on its backplate (not shown) and one ECG electrode **504** on its top face **202.** The fully standalone version of the multiparameter smart wristband **102** has wireless capabilities like Wi-Fi and Bluetooth so that it can conveniently (optionally) transmit all monitored data to other external devices **116**. In this embodiment of the invention, all data acquisition, analysis, storage, and transmission tasks may be performed by the microcontroller (not shown) that runs dedicated embedded software.

FIG. **6** illustrates an embodiment of a fully standalone version of the multiparameter smart wristband worn by a user on the left hand with the index finger of the right hand touching the top face ECG electrode for monitoring data that includes ECG data along with other external devices to which monitored data is optionally wirelessly transferred. The device **102** is worn on the left hand **104** such that the ECG electrodes on the backplate (not shown) contact the skin. Additionally, the ECG electrode **504** provided on the front face **202** is touched by the index finger of the right hand **602** to complete the ECG circuit. With this configuration, the multiparameter smart wristband **102** additionally acquires a single channel ECG waveform signal. In FIG. **6**, a zoomed version of the touchscreen display **502** is shown whereby two arterial pulse waveform signals **110**, **112** and an ECG waveform signal **604** are being monitored. In one embodiment, the device microcontroller (not shown) may detect ECG R-peaks to compute and report HR and HRV metrics with clinical-grade accuracy. Again, all monitored information may be wirelessly transferred to other external devices **116**. Finally, all data acquisition, analysis, storage, and transmission tasks may be handled by the microcontroller (not shown) running dedicated embedded software.

FIGS. **7A-7B** illustrate an example of a fully standalone version of the multiparameter smart wristband with its top face, power button, and backplate that incorporates reflective PPG arterial pulse sensors, thermopile sensor, and ECG electrodes. In this example, the device top plate **202** is additionally provided with a touchscreen display **502** and an ECG electrode **504**. Moreover, the device backplate **206** is additionally provided with two ECG electrodes **702**, **704**.

FIG. **8** illustrates an exploded view of the fully standalone version of the multiparameter smart wristband showing various components. In this example of the invention, the top plate **202** additionally accommodates the touchscreen display **502** and an ECG electrode **504**. Moreover, the backplate **206** additionally incorporates two ECG electrodes **702**, **704**. In this example embodiment, due to the addition of the touchscreen display **502** on the top face **202**, the charging coil **308** associated with the Qi wireless charging circuitry is provided just above the backplate **206**. The charging coil **308** can be located anywhere within the multiparameter smart wristband in which it will provide charging power to the rechargeable battery **306.**

FIG. **9** illustrates an operational diagram of the fully standalone version of the multiparameter smart wristband showing several components and their various connections. Here, the microcontroller **414** may be additionally interfaced with a GPS module **902** via a UART bus, a touchscreen display **502**, and a memory module **904**. The first ECG electrode **702** provided on the device backplate **206** is a left-side electrode that may be connected to the first input of an analog differential amplifier **906** whereas the second ECG electrode **704** provided on the device backplate **206** is a driven electrode that may be connected to a driving amplifier **908**. The ECG electrode **504** provided on the device top face **202** is a right-side electrode that may be connected to the second input of an analog differential amplifier **906**. In reference to FIG. **9**, the microcontroller **414** may run dedicated embedded software to independently monitor three arterial pulse waveform signals, one ECG waveform signal, user activity, and user location. Moreover, the microcontroller **414** may also run dedicated embedded software to independently analyze all data to report parameters like NIBP, SpO_2, HR, HRV, RR, temperature, user activity, and user location. The microcontroller **414** may also store information inside the memory module **904** as required. Finally, the microcontroller **414** transmits information wirelessly to the outside world via the radio transceiver **418** and antenna **420**.

With reference to FIG. **1**, Fig. **4**, FIG. **6**, and FIG. **9**, in one embodiment, data from the ACL **416**, which is synchronously collected along with the arterial pulse waveform **108**, **110**, **112** and ECG waveform **604** data, may be used to remove noise like motion artifacts from these signals to further enhance the accuracy of HR, HRV, RR, SpO_2, and NIBP estimation.

FIGS. **10A-10B** illustrate that when the multiparameter smart wristband is attached to the wrist in the correct direction, PTT values are positive. With reference to FIGS. **10A-10B**, the smart wristband **102** is attached on the left hand **104** in the correct and expected direction. As discussed earlier, the arterial pulse wave travels unidirectionally from the heart towards the fingers of the hand **104**. Therefore, the acquired GRN1 signal **1002** leads the acquired **GRN2** signal **1004** since the GRN1 PPG arterial pulse sensor (not shown) is farther away from the periphery (fingers) of the left hand **104** and the GRN2 PPG arterial pulse sensor (not shown) is closer to the periphery (fingers) of the left hand **104** underneath the device **102**. In this scenario, the PTTs computed by subtracting the temporal locations of the peaks of the GRN1 signal **1002** from the temporal locations of the peaks of the GRN2 signal **1004** result in positive values **1006**.

FIGS. **11A-11B** illustrate that when the multiparameter smart wristband is attached to the wrist in the incorrect direction, PTT values are negative. In this scenario, the PTTs computed by subtracting the temporal locations of the peaks of the GRN1 signal **1002** from the temporal locations of the peaks of the GRN2 signal **1004** result in negative values **1102**. In one embodiment, this phenomenon is utilized to automatically detect whether the user has attached the device **102** on the wrist in the correct direction or not. Moreover, when an incorrect attachment is detected and the computed PTT values are negative, they may be automatically corrected to positive values. In addition to the foregoing, or alternatively, if PTT values of less than 0 are detected, it implies that these values are negative and an alert "Smart wristband attached in the correct direction" may be generated for the user. Moreover, even if the wristband is not adjusted in the proper direction, the negative PTT values may be corrected by multiplying them by negative 1. Then the corrected PTT values may be used for further computations as needed. An example of a simplified iOS Swift code that analyzes negative PTT values **1102** to automatically detect and alert for wrong attachment of the multiparameter smart wristband **102** on the wrist and also corrects these values is presented below:

Smart Wristband Attachment Direction Detection and PTT Correction

```
var PTT = [-263, -253, -254, -250, -261]
```

```
var negativeCount = 0
for i in 0...(PTT.count-1) {
   if (PTT[i] < 0) {
      negativeCount += 1
   }
}
if (negativeCount>0) {
   print ("Smart wristband attached in the incorrect direction")
   for i in 0...(PTT.count-1) {
      PTT[i] = -PTT[i]
   }
} else {
   print ("Smart wristband attached in the correct direction")
}
print ("Corrected PTTs =", PTT)
```

FIG. **12** illustrates an exemplary PWM technique that may be utilized inside the multiparameter smart wristband for switching LEDs associated with the three PD sensors and synchronously reading data from these PD sensors. In this example, the three LED clusters **210**, **214**, **218** are switched on and off utilizing three PWM signals **1202**, **1204**, **1206** that are generated by three DIO channels (not shown) of the microcontroller **414**. The three ADC channels (ADC0, ADC1, ADC2) of the microcontroller **414** that are interfaced with the three PDs **208**, **212**, **216** may be programmed to read a data sample only when the corresponding PWM signal is high. In this example, each LED cluster is on for 1100 ms and off for 8900 ms, and a data read occurs exactly at the middle of the on period. Moreover, there is a phase difference of 1600 ms between the three PWM signals **1202**, **1204**, **1206**. This particular PWM scheme therefore results in a data sampling rate of 100 Hz each for the three acquired arterial pulse waveform signals. As discussed earlier, the described PWM technique allows that: (i) the LEDs do not heat up and (ii) the LEDs associated with one PD do not cause interference in other PDs. The described PWM technique therefore may provide the acquisition of high-quality clinical-grade arterial pulse waveform data. Other PWM techniques having different data sample rates, on/off periods and phase differences may also be used.

FIG. **13** illustrates an operational diagram of an exemplary AGC scheme that is utilized inside the multiparameter smart wristband to standardize arterial pulse waveform signal quality and fidelity over all users. In this example, the signal from the GRN1 PD **208** is amplified by the amplifier **408** after which it is fed to the ADC channel ADC0 of the microcontroller **414**. The gain of the differential amplifier **408** may be controlled by an I2C potentiometer R_6 **1302** that is connected to an I2C port of the microcontroller **414**. The non-inverting gain of the amplifier **408** may be governed by R_5 **1304** and the I2C potentiometer R_6 **1302** and represented as $G = (1 + R_5/R_6)$. In one embodiment, the microcontroller **414** computes a peak-to-peak amplitude of the GRN1 arterial pulse waveform signal and automatically alters the resistance of R_6 **1302** via the I2C bus to change the gain of the amplifier **408** such that the peak-to-peak amplitude of the GRN1 signal always stays above 2.0 V. This AGC technique may be employed to standardize all three arterial pulse waveform signals acquired from the three PDs **208**, **212**, **216**, resulting in the acquisition of clinical-grade high-fidelity arterial pulse waveform data from all users.

In another embodiment, three sliders may be provided on the display **114** of the tethered mobile device **106** and/or on the touchscreen display **502** of the smart wristband **102**. These three sliders may be in communication with the three I2C potentiometers that control the gains of the three PD amplifiers **408**, **410**, **412**. In one example, the user eyeballs the incoming data and then manually adjusts the gain of the three arterial pulse waveform signals using these three sliders to obtain clinical-grade high-fidelity arterial pulse waveform data.

FIG. **14** illustrates an operational diagram of an example AGC scheme that is utilized inside the multiparameter smart wristband to standardize ECG signal quality and fidelity over all users. The gain control amplifier in this embodiment is an I2C potentiometer R_{10} **1402** that controls the gain of the ECG differential amplifier **906** in conjunction with R_{11} **1404**. Again, the gain may be controlled automatically via the microcontroller **414** and/or manually via a user interface (UI) slider (as described above for arterial pulse waveform data) to obtain high-fidelity ECG signals for all users.

FIG. **15** illustrates an exemplary flowchart depicting the method of manual and continuous monitoring accomplished by the multiparameter smart wristband. The device is switched on at block **1502**. At block **1504**, if the monitoring mode is not continuous, then the program flow goes to block **1506** where temperature data is collected using the thermopile sensor **220** for 10 seconds. Then block **1508** checks whether the temperature data collected is valid or not and demands recollection of the temperature data via block **1506** until valid temperature data is collected. If block **1508** determines that the collected temperature data is valid, the program flow proceeds to block **1510** that checks whether ECG on demand is on or off. The ECG on demand block **1510** essentially checks whether the user is touching the ECG electrode **504** on the device top face **202** with a finger of the other hand without which ECG data acquisition cannot be accomplished. If at block **1510**, ECG on demand at is on, then all data including ECG data is collected for 30 seconds or other time period at block **1520**. Block **1522** then checks if collected data is valid – if not valid, program flow goes back to the ECG on demand block **1510**, otherwise program flow goes to block **1524** that analyzes data, calculates and displays parameters, and optionally sends information to other external devices **116**. Once a manual monitoring session is completed, block **1526** switches off the device. If ECG on demand at block **1510** is off, the program flow proceeds in a similar manner through blocks **1512**, **1514**, **1516**, **1518**, without ECG data acquisition. At block **1504**, if the monitoring mode is continuous, then the program flow proceeds in a similar manner through blocks **1528**, **1530**, **1532**, **1534**, **1536** without ECG data acquisition. The block **1538** instructs the program to pause for 15 minutes after which the flow goes back to block **1504**. If block **1504** maintains the monitoring mode as continuous, data is automatically collected, analyzed, displayed, and transmitted every 15 minutes.

FIG. **16** illustrates an example flowchart depicting the generation of various health alerts by the multiparameter smart wristband. At block **1602**, the program prepares physiological and ACL data for analysis. Most normal ranges of physiological parameters are defined for the resting state. Therefore, at block **1604** the program utilizes the ACL information to detect if the subject is at rest or not. If block **1604** detects that the subject is not at rest, no alerts are generated as defined by block **1606**. If block **1604** determines that the subject is at rest, the program flow goes to blocks **1608**, **1610**, **1612**, **1614**, **1616** that determine whether various physiological parameters are within their clinically specified normal ranges or not. If the physiological parameters are within the desired ranges, then no alerts are generated as described by blocks **1620**, **1624**, **1628**, **1632**, **1636**. Conversely, if the physiological parameters are outside the desired ranges, then alerts are generated as described by blocks **1618**, **1622**, **1626**, **1630**, **1634**. For example, if the resting HR is outside the 60-100 BPM range as defined by block **1608**, then a bradycardia or tachycardia alert is generated as described by block **1618**.

FIG. **17** illustrates examples of various locations on the human body where wearables employing the underlying design and principle of the multiparameter smart wristband can be attached to undertake monitoring. As illustrated in **1702**, the multiparameter smart wristband **102** can be worn around the left wrist for monitoring data. As illustrated in **1704**, the multiparameter smart wristband **102** can be worn around the right upper arm for monitoring data. Finally, as illustrated in **1706**, the multiparameter smart wristband **102** can be worn around the left ankle for monitoring data. These examples demonstrate that the disclosed multiparameter smart wristband **102** and/or similar wearable devices can be attached at various locations along the 4 limbs to accomplish manual or continuous multiparameter physiological monitoring.

FIGS. **18A-18B** illustrate the multiparameter smart wristband and the fully standalone version of the multiparameter smart wristband being charged on two different kinds of wireless charging units. In one example, the multiparameter smart wristband **102** that does not have a touchscreen display is charged upside down with its top face touching the top of Qi wirelesses charger **1802**. With this charging configuration, the charging status indicator LEDs **222** are conveniently visible to the user. In another example, the multiparameter smart wristband **102** with a touchscreen display is charged with its backplate touching the top of a Qi wirelesses charger **1804**. With this charging configuration, the charging status indicator LED **1806** provided on the wireless charger **1804** is conveniently visible to the user.

The specific examples provided herein relate to a multiparameter smart wristband for physiological monitoring, however, the materials, methods of application and arrangements of the invention can be varied. For example, any time periods, frequencies, and sampling rates mentioned here are variable and can be adjusted. As a further variant, the biosensors could be snugly fitted flush with the backplate. In another variant, a waterproof epoxy could be used to internally seal the PDs and/or LEDs, which would assist with water resistance.

In another variation, the custom PCB may be provided with an accelerometer chip that communicates with the microcontroller via the I2C bus. The microcontroller may acquire X, Y, Z axes data related to subject motion and posture using the accelerometer chip via the I2C bus. Since the accelerometer data may be synchronously collected with PPG waveform data, it may also be used to remove noise like motion artifacts from PPG data to increase accuracy of PR, SpO_2 and BP estimation. The accelerometer and related algorithms may be used to track and report motion and its intensity. Moreover, this information may also be used to remove biosensor noise that is created by motion artifacts to enhance overall measurement accuracy.

In a further variation, a thermistor or other temperature sensor could be used instead of a thermopile sensor. The voltage across the thermistor that characterizes the body temperature may be acquired by an ADC on the microcontroller. Voltage data collected from the thermistor may be used to determine the thermistor’s resistance. Then, the thermistor’s resistance-temperature look-up table may be used to report body temperature.

In yet a further variation, the microcontroller may time stamp acquired data and wirelessly stream this data to a base station, such as a tablet or smartphone via a Bluetooth chip which may be connected to a UART port. The microcontroller on the device may be further provided with a sync-able real-time clock (RTC). All date-stamped data can be reported and stored in comma-separated value (CSV) format whereby the first column exports the time stamps while subsequent columns report values of PPG waveform and other data. Time stamping could be accomplished using the microcontroller RTC in conjunction with the base station clock.

In yet a further variation, the ECG electrode locations and numbers can vary. For example, the multiparameter smart wristband can have one ECG electrode on the bottom and two ECG electrodes on the top. In such a configuration, one ECG electrode on the backplate would contact the skin, while two ECG electrodes provided on the front face would be touched by the index finger to complete the ECG circuit.

Various programming languages such as assembly language, embedded C, C, Java, Swift, and Python may be used to develop software for accomplishing data analysis on the microcontroller and base station or external devices. The software could provide functionality such that data analysis can be done in real time on live data as well as on a post-hoc basis on stored data.

Furthermore, a structured software development kit (SDK) man be architected to enable third parties to develop software for accessing measurements from the data. The SDK documentation could outline the protocol, interface, commands, and system responses. A dynamically linked library could also be constructed and included with the SDK.

The components could be selected such that a unit cost of less than $20 (for on-patient portion excluding GPS and display) for large quantities ($\geq$ 1K) is possible. Hence the device can be realized and fabricated as a low-cost yet effective multiparameter physiological monitor.

As a further variant, the smart wristband **102** of FIGS. **1** to **4** may incorporate the ECG sensors therein and further monitor ECG signals.

The scope of the claims should not be limited by the preferred embodiments set forth in the examples but should be given the broadest interpretation consistent with the description as a whole.

What is claimed is:

1. A smart wristband for multiparameter physiological monitoring comprising:

   biosensors configured to contact skin of a user in at least three separate locations; and

   a microcontroller in communication with the biosensors and configured to determine multiple vital signs from data from the biosensors.

2. The smart wristband of claim 1 wherein the biosensors comprise at least three photoplethysmography (PPG) sensors.

3. The smart wristband of claim 2 wherein the PPG sensors each include at least three LEDs and at least one photodiode (PD) sensor.

4. The smart wristband of any one of claims 1 to 3 wherein the biosensors further comprise a temperature sensor.

5. The smart wristband of any one of claims 1 to 4 wherein the biosensors further comprise at least three ECG electrodes.

6. The smart wristband of claim 5 further comprising a backplate and a top face, wherein two ECG electrodes are in the backplate, while one ECG electrode is in the top face.

7. The smart wristband of any one of claims 1 to 6 wherein the vital signs include HR, HRV, SpO_2, NIBP, RR, body temperature and arterial pulse, along with electrocardiogram (ECG) monitoring.

8. The smart wristband of any one of claims 1 to 7 further comprising a backplate, a top face and a strap, wherein the strap includes a gasket that is sealed around the backplate, the top face, the microcontroller and the biosensors.

9. The smart wristband of any one of claims 1 to 8 further comprising a light for illuminating the display.

10. The smart wristband of any one of claims 1 to 9 further comprising a transceiver configured for wireless communication.

11. The smart wristband of any one of claims 1 to 10 further comprising a display for displaying the vital signs.

12. The smart wristband of any one of claims 1 to 11 further comprising a rechargeable battery.

13. The smart wristband of any one of claims 1 to 12 wherein the external device and the microcontroller are configured to detect negative pulse transit times in measurements from the biosensors, and if negative pulse transit times are detected, to provide an alert and automatically correct the negative pulse transit times by multiplying by -1.

14. The smart wristband of any one of claims 1 to 13 further comprising an accelerometer sensor.

15. The smart wristband of claim 14 wherein the microcontroller acquires user activity data via the accelerometer sensor.

16. The smart wristband of claim 10 wherein the microcontroller is configured to utilize the transceiver to send the vital signs or data in real-time to an external device.

17. The smart wristband of claim 2 or 3 further comprising a transceiver for wireless communication; wherein the microcontroller uses the transceiver to send the vital signs or data in real-time to an external device; and wherein the microcontroller is configured to receive at least three arterial pulse waveform signals via the at least three PPG sensors.

18. The smart wristband of claim 17 wherein

    the external device analyzes the at least three arterial pulse waveform signals to compute at least three pulse transit time (PTT), at least three pulse wave velocity (PWV), and at least three pulse amplitude metrics and combines these metrics to evaluate and report non-invasive blood pressure (NIBP) with clinical-grade accuracy;

the external device analyzes the at least three arterial pulse waveform signals to compute at least three peak-to-peak interval (PPI) metrics and combines these metrics using various statistical and other methods to evaluate and report heart rate (HR) with clinical-grade accuracy;

the external device analyzes the respiratory sinus arrythmia (RSA) induced modulations in the amplitudes of the at least three pulse waveform signals, at least three PPI signals, and at least three PTT signals to compute at least nine respiration rate (RR) metrics, and combines these metrics using various statistical and other methods to evaluate and report RR with clinical-grade accuracy;

the external device analyzes the at least three pulse waveform signals of different wavelengths to compute at least two blood oxygen saturation (SpO_2) metrics and combines these metrics using various statistical and other methods to evaluate and report SpO_2 with clinical-grade accuracy;

the external device analyzes accelerometer data to accurately report user activity level; and

the external device utilizes global positioning system (GPS) capabilities to accurately report user location.

19. The smart wristband of claim 4 wherein temperature sensor data from the temperature sensor is aggregated to report body temperature with clinical-grade accuracy.

20. The smart wristband of any one of claims 1 to 20 further comprising a GPS module, a memory module, and a touchscreen display.

21. The smart wristband of claim 20 wherein the microcontroller is configured to acquire GPS data via the GPS module and analyzes the GPS data to accurately report user location.

22. The smart wristband of claim 20 wherein

the microcontroller is configured to:

receive at least three arterial pulse waveform signals via the at least three PPG sensors;

analyze the at least three arterial pulse waveform signals to compute at least three pulse transit time (PTT), at least three pulse wave velocity (PWV), and at least three pulse amplitude metrics and combine the pulse amplitude metrics to evaluate and report non-invasive blood pressure (NIBP) with clinical-grade accuracy;

analyze the at least three arterial pulse waveform signals to compute at least three peak-to-peak interval (PPI) metrics and combine the metrics to evaluate and report heart rate (HR) with clinical-grade accuracy;

analyze respiratory sinus arrythmia (RSA) induced modulations in the amplitudes of the at least three arterial pulse waveform signals, at least three PPI signals, and at least three PTT signals to compute at least nine respiration rate (RR) metrics, and to combine the RR metrics using various statistical and other methods to evaluate and report RR with clinical-grade accuracy;

analyze the at least three pulse waveform signals of different wavelengths to compute at least two blood oxygen saturation (SpO_2) metrics and combines the SpO_2 metrics to evaluate and report SpO_2 with clinical-grade accuracy; and

analyze accelerometer data to accurately report user activity level.

23. The smart wristband of claim 5 or 6 wherein the microcontroller is configured to receive an ECG waveform signal via the at least three ECG electrodes whenever two of the at least three electrodes contact the skin of the user on one side of a body of the user and one of these electrodes also contact the skin of the user on the other side of the body.

24. The smart wristband of claim 23 wherein the microcontroller is configured to analyze the ECG waveform signal to report parameters with clinical-grade accuracy, the parameters including HR and HR variability (HRV).

25. The smart wristband of claim 2 or 3 further comprising a backplate and a top face, wherein the at least three PPG sensors are spread across a length of the backplate and

configured to measure at least three arterial pulse waveform signals on at least three distinct locations on the wrist enabling measurement of at least three PTT signals.

26. The smart wristband of claim 6 wherein one of the two ECG electrodes in the backplate is a driven electrode.

27. The smart wristband of claim 16 or 17 wherein the external device is configured to display data, store data, and/or transmit data to other external devices.

28. The smart wristband of claim 21 wherein the microcontroller is configured to display data, store data, and/or transmit data to other external devices.

29. The smart wristband of any one of claims 1 to 28 further comprising a strap made of elastomeric material and configured as a single piece, such that a gasket is integrated with the strap.

30. The smart wristband of any one of claims 1 to 29 wherein the microcontroller is configured to perform manual intermittent or continuous physiological monitoring as per user specified monitoring frequency.

31. The smart wristband of any one of claims 1 to 30 wherein the microcontroller is configured to generate health alerts based on the multiple vital signs from the data from the biosensors.

32. The smart wristband of claim 3 further comprising a backplate and a top face, wherein the backplate comprises light barriers between each of the LEDs and the at least one PD sensor, and individual transparent lenses to separately encapsulate each of the LEDs and the at least one PD sensor.

33. The smart wristband of claim 32 wherein the backplate is manufactured utilizing an industrial co-moulding process and formed from acrylonitrile butadiene styrene (ABS), while each of the individual transparent lenses is moulded using transparent materials.

34. The smart wristband of claim 2 or 3 wherein the microcontroller is configured to receive at least three arterial pulse waveform signals via the at least three PPG sensors and utilize automatic gain control (AGC) to standardize quality and fidelity of the three arterial pulse waveform signals over all users, wherein gains of the three arterial pulse waveform signals are controlled automatically by the microcontroller and/or manually by the user by varying sliders on a user interface (UI) that are in communication with the microcontroller.

35. The smart wristband of claim 5 or 6 wherein the microcontroller is configured to utilize AGC to standardize quality and fidelity of the ECG signal from the ECG electrodes over all users, wherein gains of the ECG signal are controlled automatically by the microcontroller and/or manually by the user by varying a slider on a the UI that is in communication with the microcontroller.

36. The smart wristband of claim 3 wherein the microcontroller uses pulse width modulation (PWM) technique to control the LEDs of the at least three PPG sensors and synchronously read data from the at least one PD sensor to minimize interference between unassociated LEDs and PDs and to prevent the LEDs from heating up.

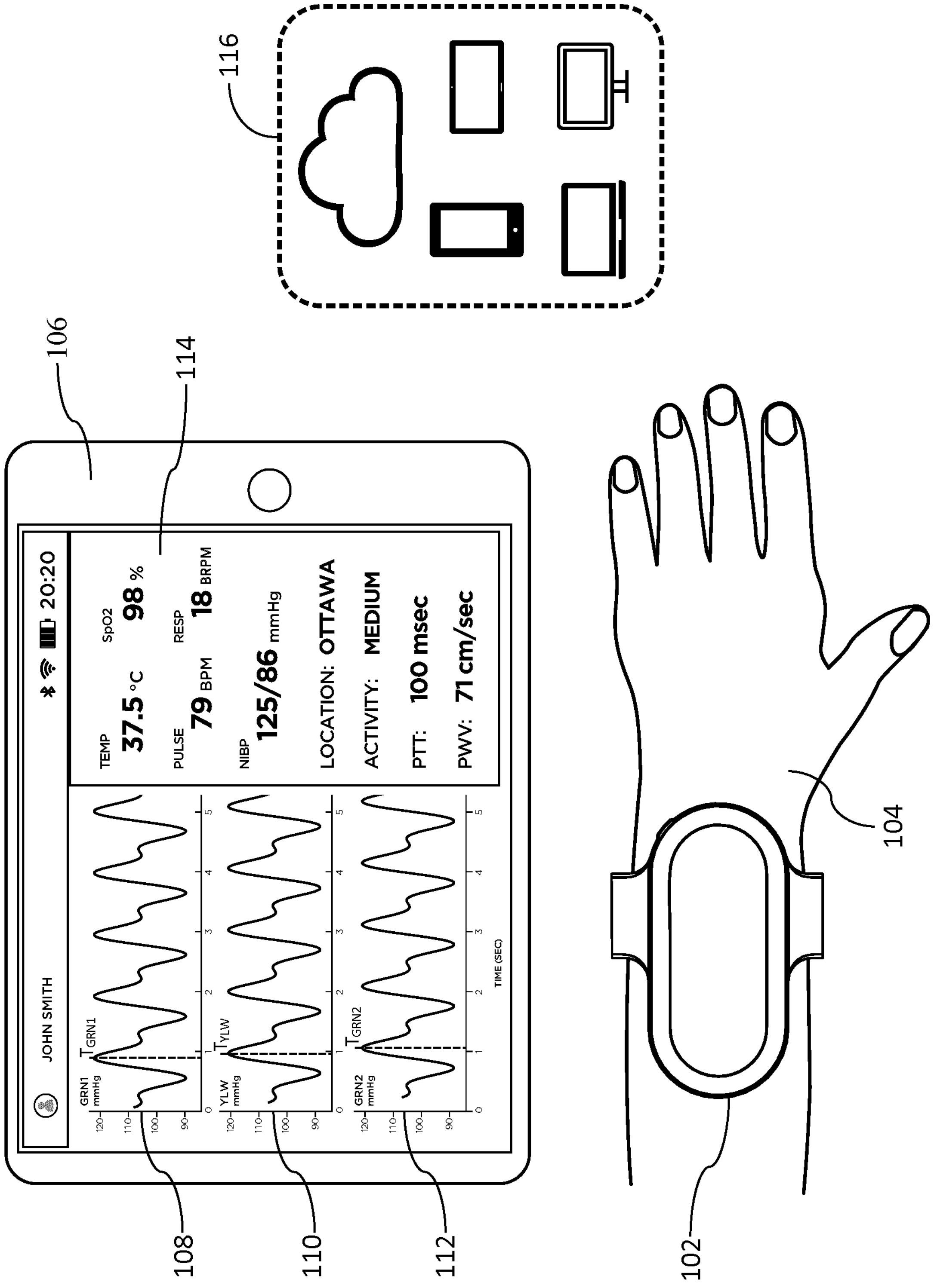
37. The smart wristband of any one of claims 1 to 36 further comprising wireless charging circuitry configured to be wirelessly charged with a wireless charging unit.

38. The smart wristband of any one of claims 1 to 37 wherein the device is configured to be attached at various locations along limbs of the user.

39. The smart wristband of claim 16 or 17 wherein the external device is selected from the group consisting of a mobile device, a smartphone, a tablet, and a computer.

40. The smart wristband of claim 5 or 6 further comprising an accelerometer sensor, wherein the microcontroller is configured to receive at least three arterial pulse waveform signals via the at least three PPG sensors and wherein the microcontroller uses synchronously collected data from the accelerometer sensor to remove noise such as motion artifacts from the at least three pulse waveform signals and the ECG

waveform signal to further increase accuracy of evaluation of parameters like HR, HRV, RR, SpO_2, and NIBP.



JOHN SMITH

20:20

TEMP 37.5 °C

SpO2 98 %

PULSE 79 BPM

RESP 18 BRPM

NIBP 125/86 mmHg

LOCATION: OTTAWA

ACTIVITY: MEDIUM

PTT: 100 msec

PWV: 71 cm/sec

FIG. 1

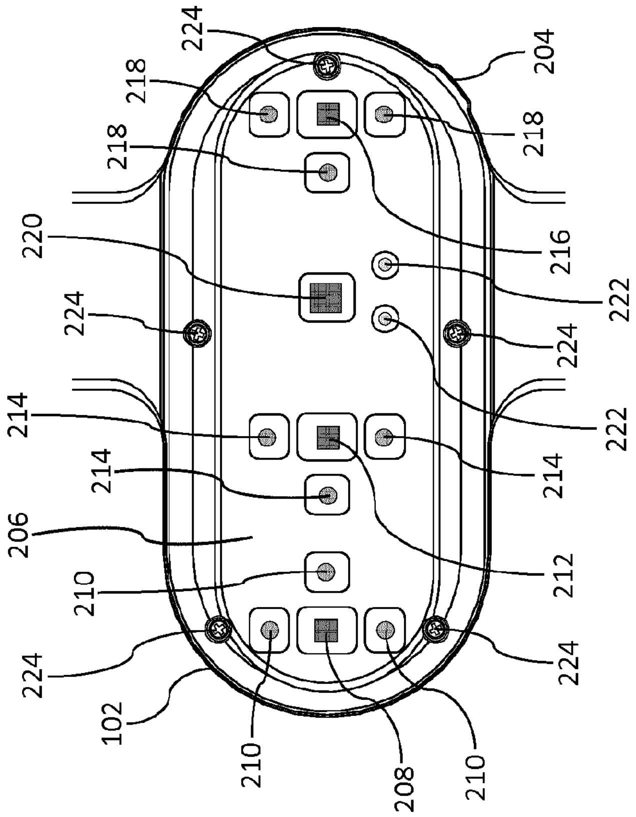

224
218
218
218
204
220
216
222
224
224
222
214
214
214
206
212
210
224
224
102
210
208
210

FIG. 2B

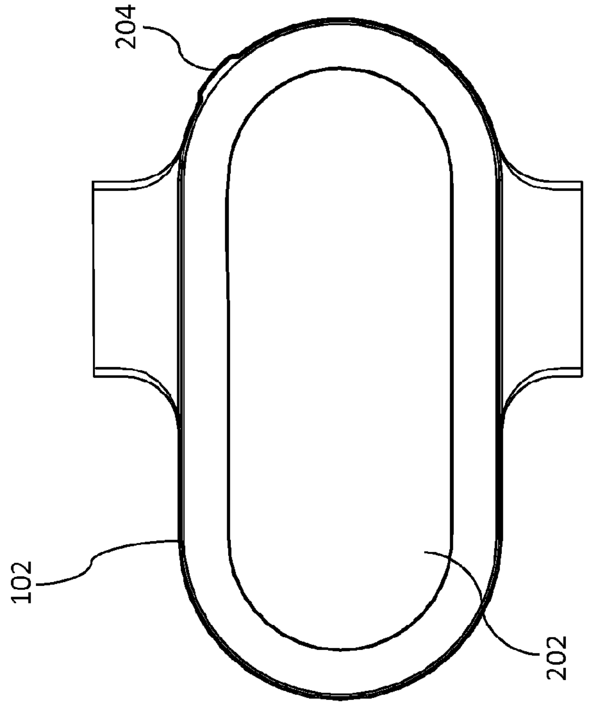
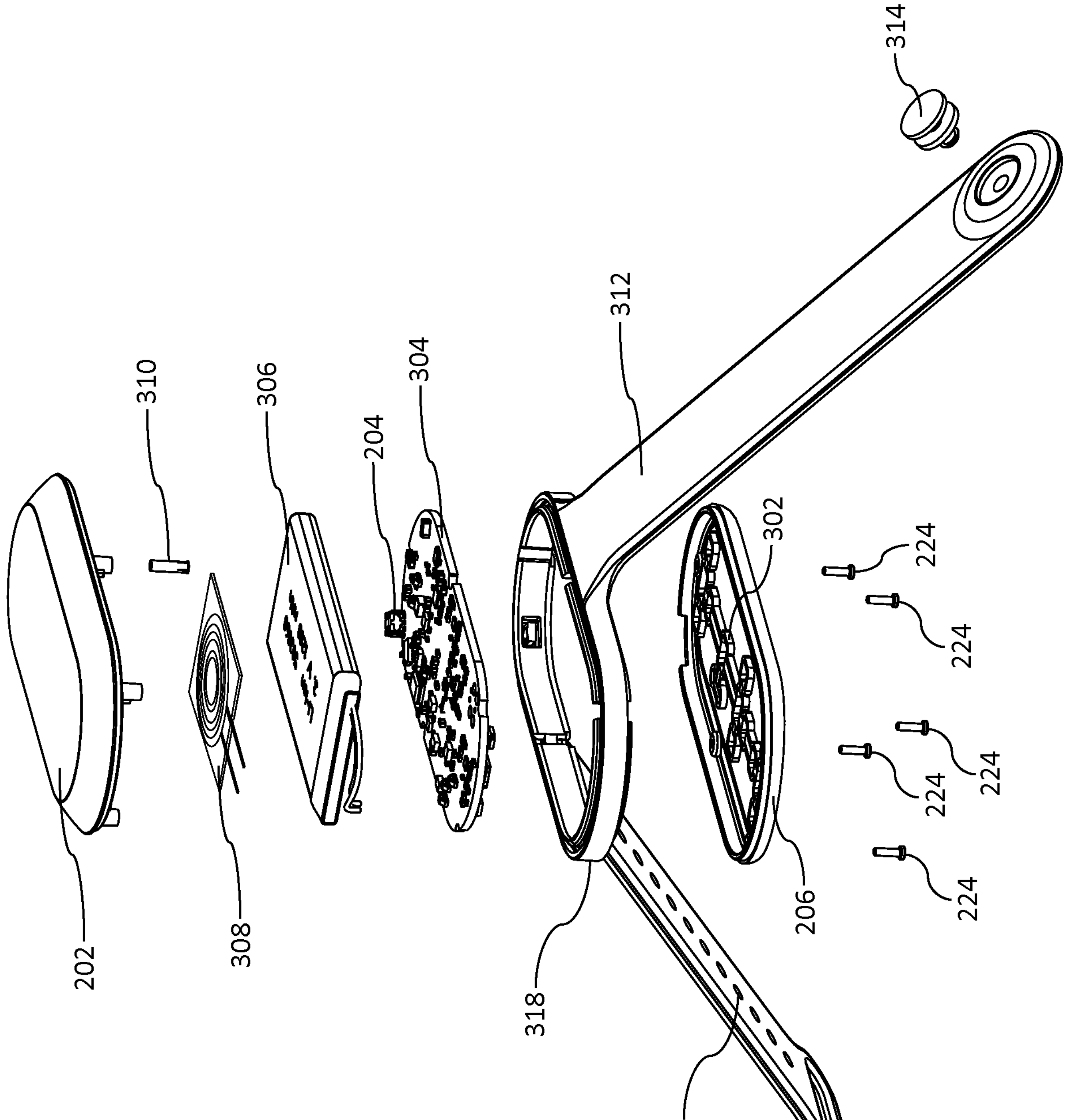

204
102
202

FIG. 2A


314
312
310
306
204
304
302
224
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224
224
224
202
308
318
316
206

FIG. 3

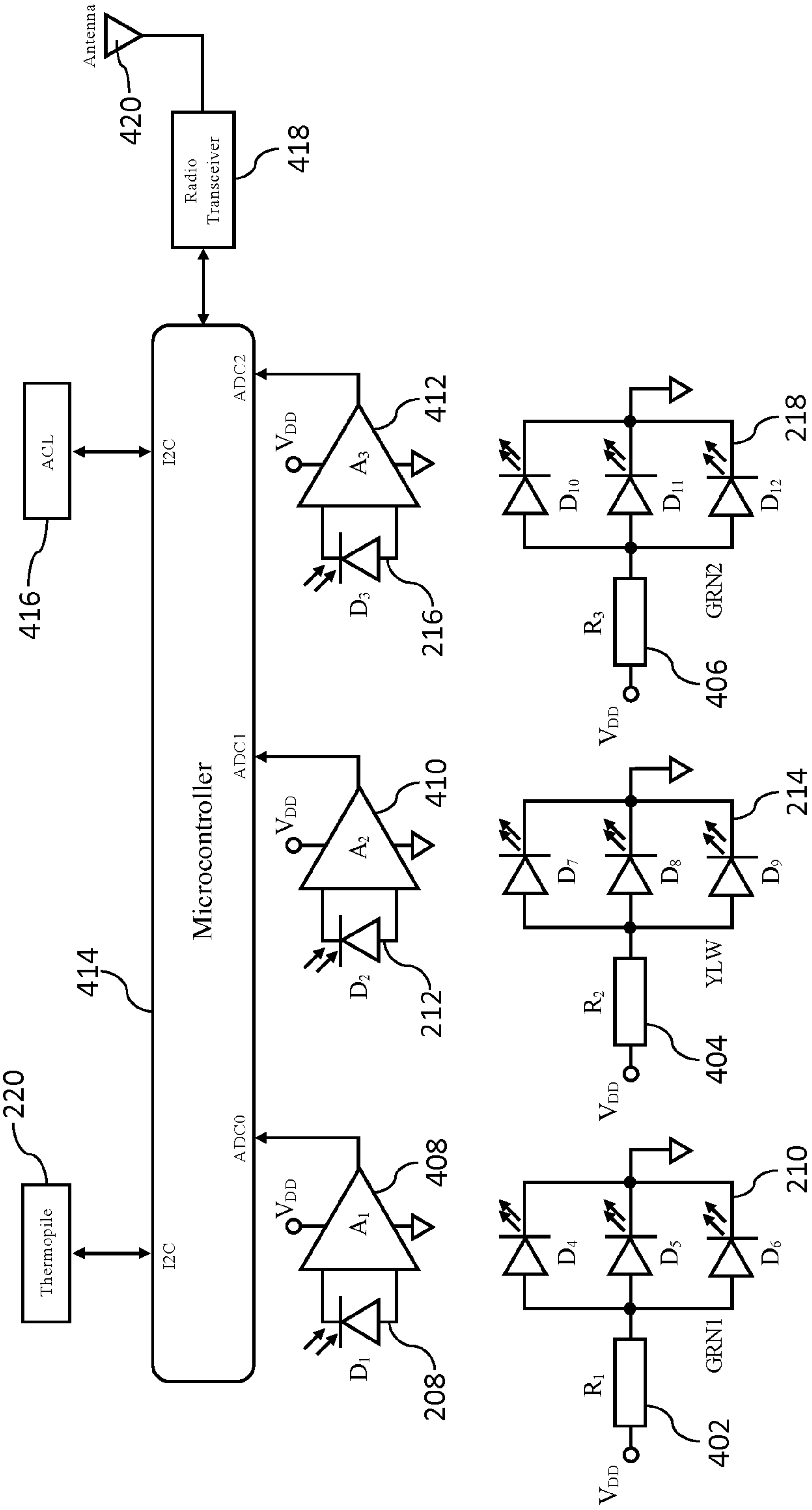
Antenna
420
Radio Transceiver
418
ACL
416
Thermopile
220
I2C
I2C
Microcontroller
414
ADC0
ADC1
ADC2
V_DD
V_DD
V_DD
A1
A2
A3
408
410
412
D1
D2
D3
208
212
216
D4
D5
D6
D7
D8
D9
D10
D11
D12
210
214
218
R1
R2
R3
402
404
406
GRN1
YLW
GRN2
V_DD
V_DD
V_DD

FIG. 4

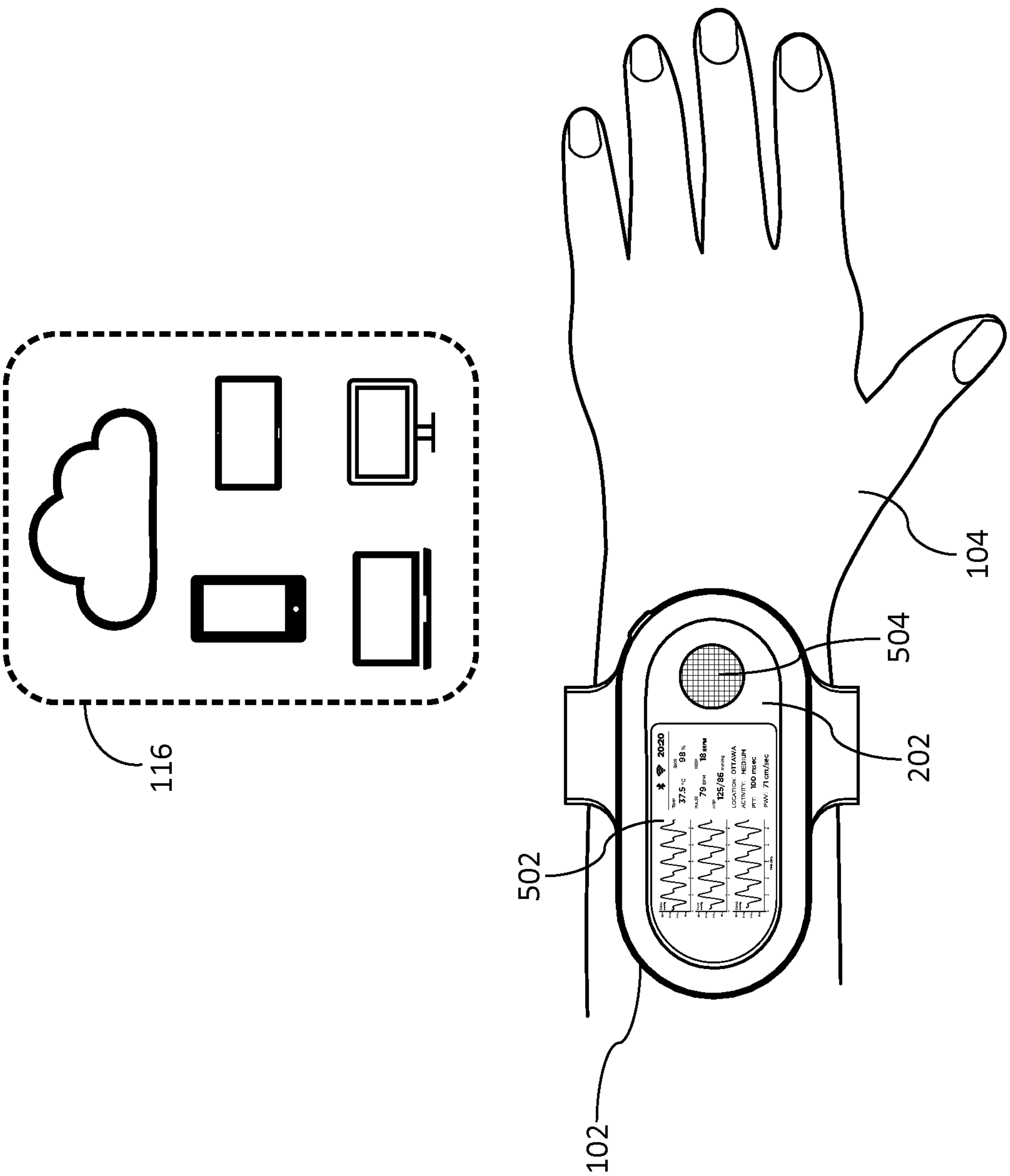
116
104
504
202
502
102
20:20
TEMP 37.5 °C
SpO2 98 %
PULSE 79 BPM
RESP 18 BRPM
NIBP 125/86 mmHg
LOCATION: OTTAWA
ACTIVITY: MEDIUM
PTT: 100 msec
PWV: 71 cm/sec

FIG. 5

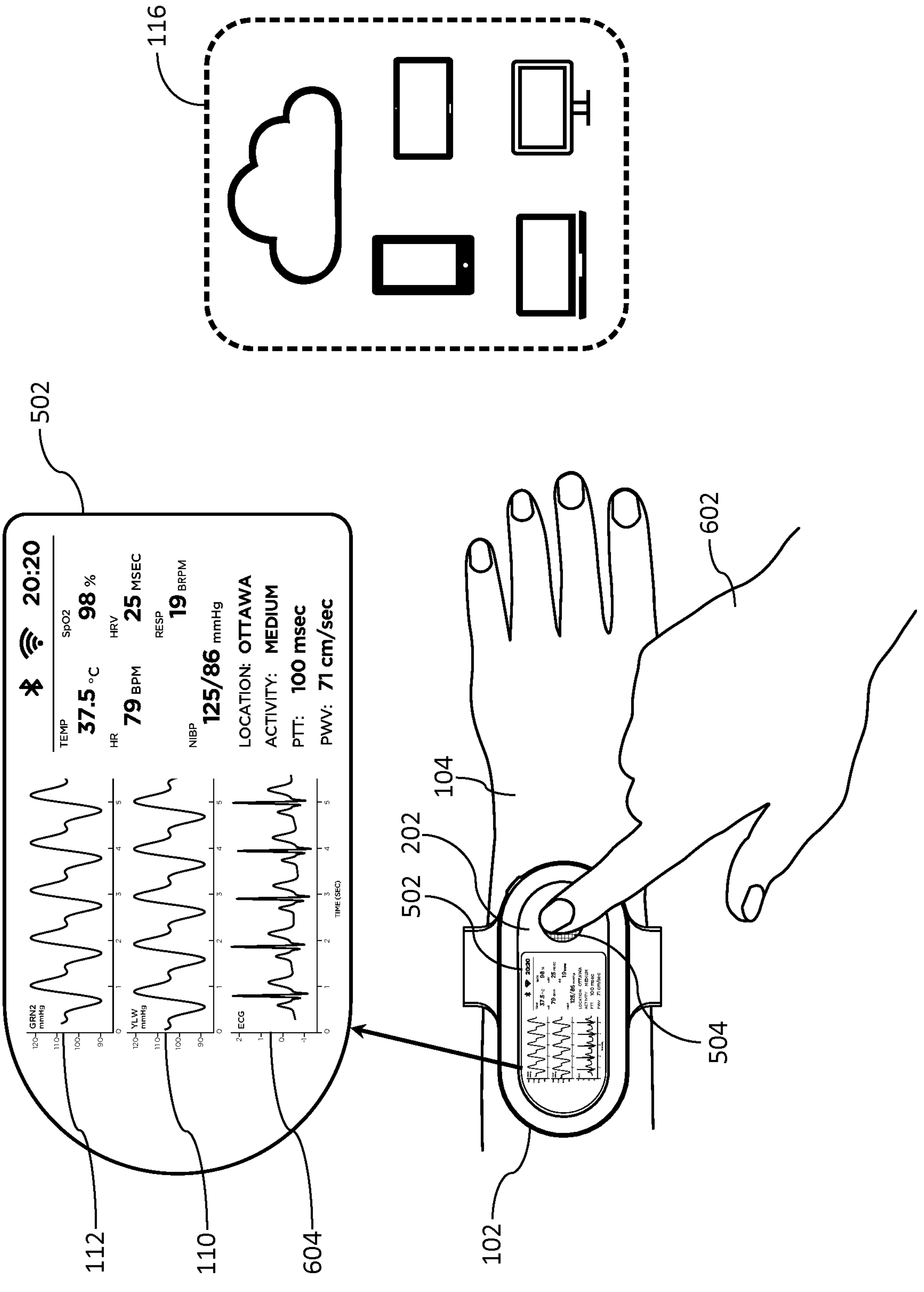
116
502
20:20
TEMP
37.5 °C
SpO2
98 %
HR
79 BPM
HRV
25 MSEC
RESP
19 BRPM
NIBP
125/86 mmHg
LOCATION: OTTAWA
ACTIVITY: MEDIUM
PTT: 100 msec
PWV: 71 cm/sec
GRN2 mmHg
120
110
100
90
0
YLW mmHg
120
110
100
90
0
ECG
2
1
0
-1
0
1
2
3
4
5
TIME (SEC)
112
110
604
602
104
202
502
504
102

FIG. 6

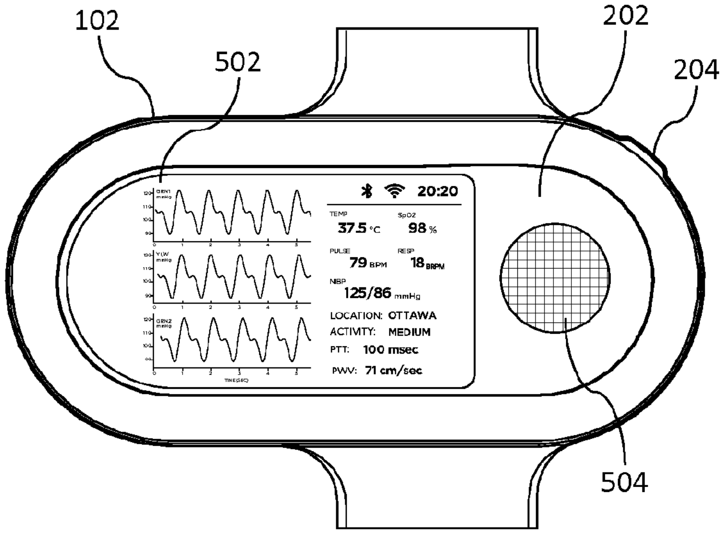
102
502
202
204
504
GRN1 mmHg
120
110
100
90
0
1
2
3
4
5
YLW mmHg
GRN2 mmHg
TIME(SEC)
20:20
TEMP
37.5 °C
SpO2
98 %
PULSE
79 BPM
RESP
18 BRPM
NBP
125/86 mmHg
LOCATION: OTTAWA
ACTIVITY: MEDIUM
PTT: 100 msec
PWV: 71 cm/sec

FIG. 7A

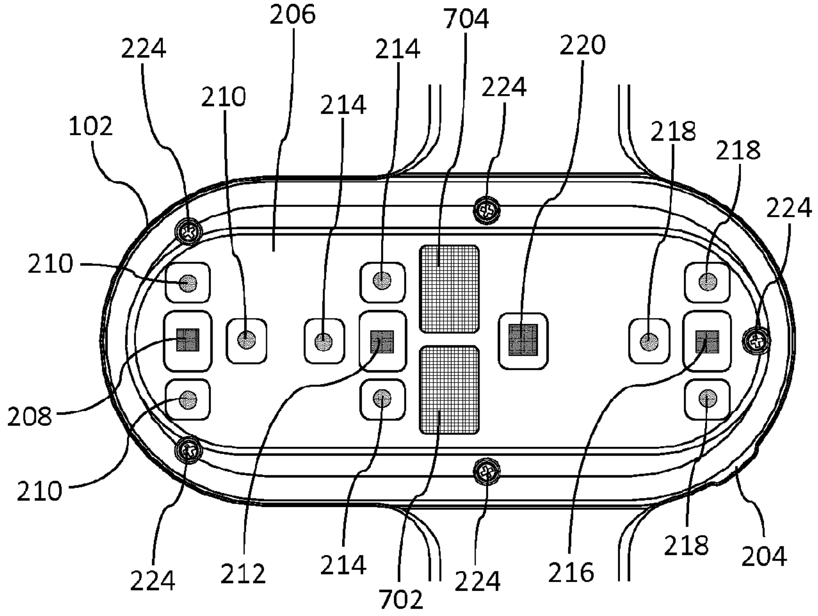
206
704
224
214
220
210
214
224
102
218
218
224
210
208
210
224
212
214
702
224
216
218
204

FIG. 7B

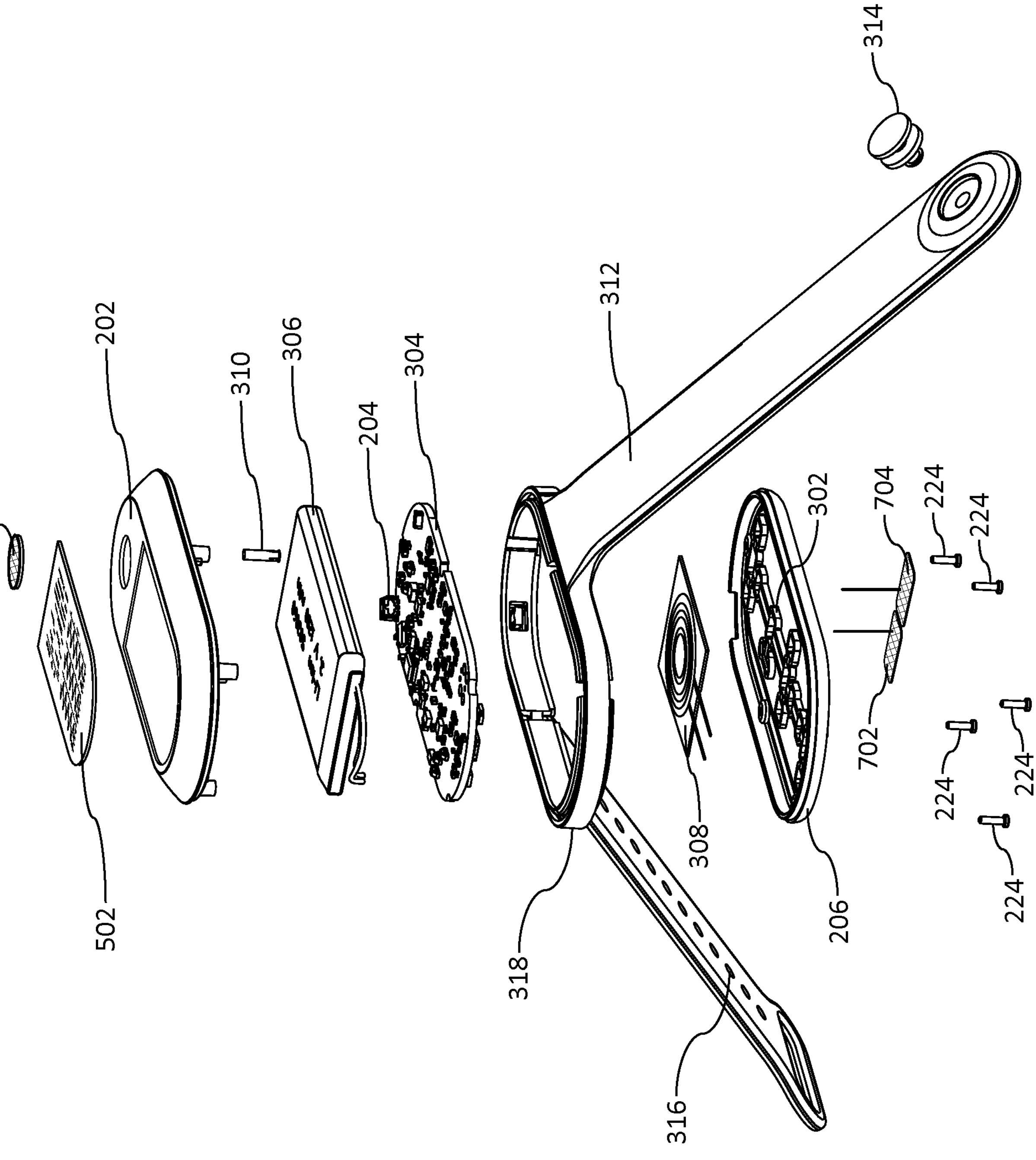
504
502
202
310
306
204
304
312
314
318
316
308
302
206
704
702
224
224
224
224
224

FIG. 8

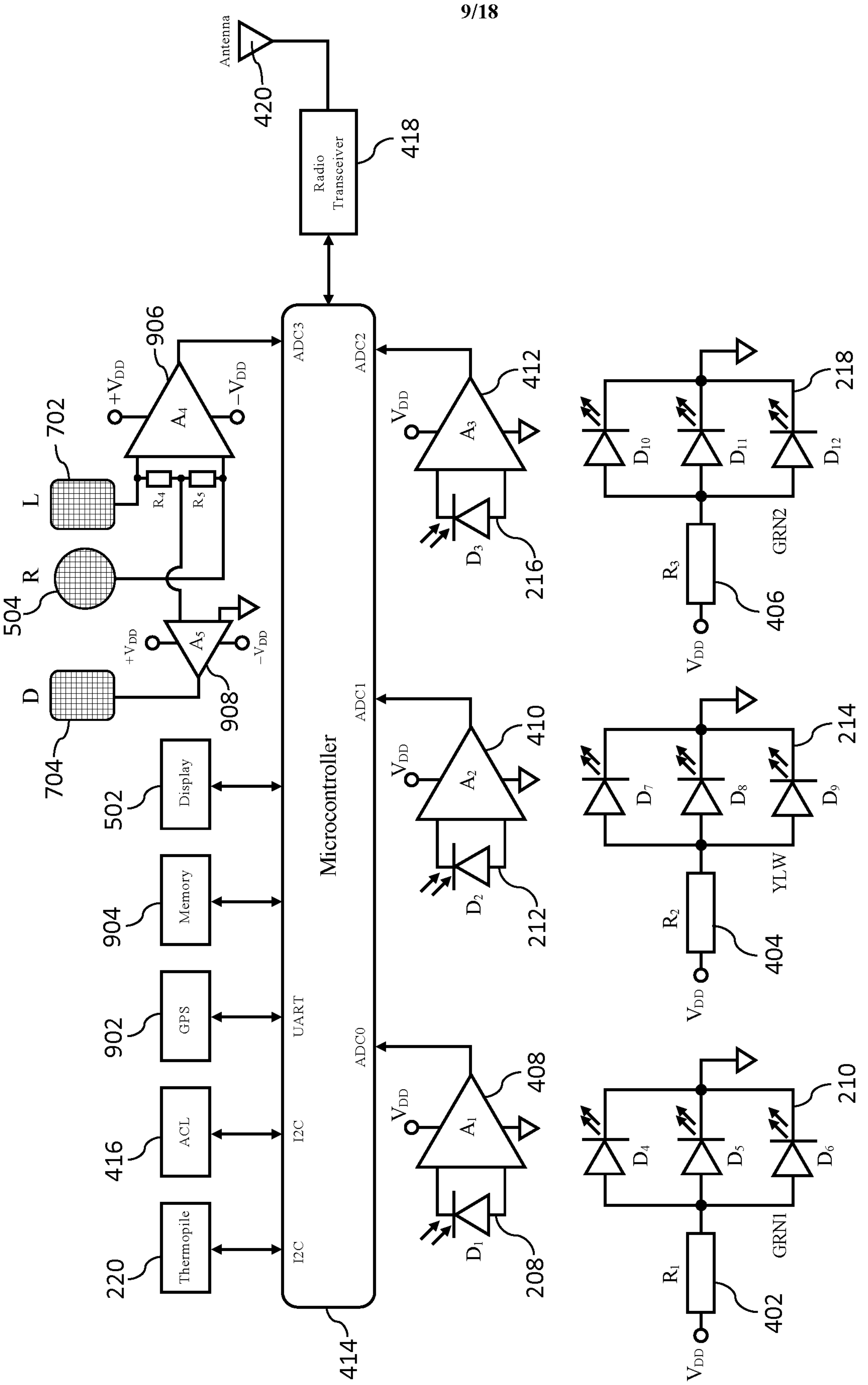
Antenna
420
Radio Transceiver
418
Microcontroller
414
ADC0
ADC1
ADC2
ADC3
UART
I2C
I2C
Thermopile
220
ACL
416
GPS
902
Memory
904
Display
502
D
704
R
504
L
702
R_4
R_5
A_4
906
$+V_{DD}$
$-V_{DD}$
A_5
908
$+V_{DD}$
$-V_{DD}$
A_1
408
A_2
410
A_3
412
V_{DD}
V_{DD}
V_{DD}
D_1
208
D_2
212
D_3
216
D_4
D_5
D_6
210
D_7
D_8
D_9
214
D_{10}
D_{11}
D_{12}
218
R_1
402
R_2
404
R_3
406
V_{DD}
V_{DD}
V_{DD}
GRN1
YLW
GRN2

FIG. 9

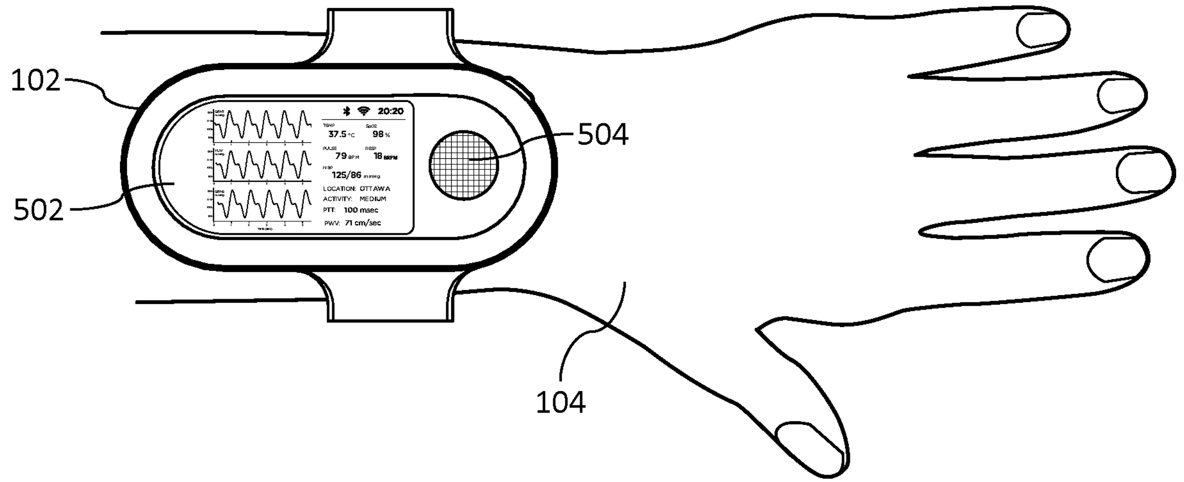

FIG. 10A

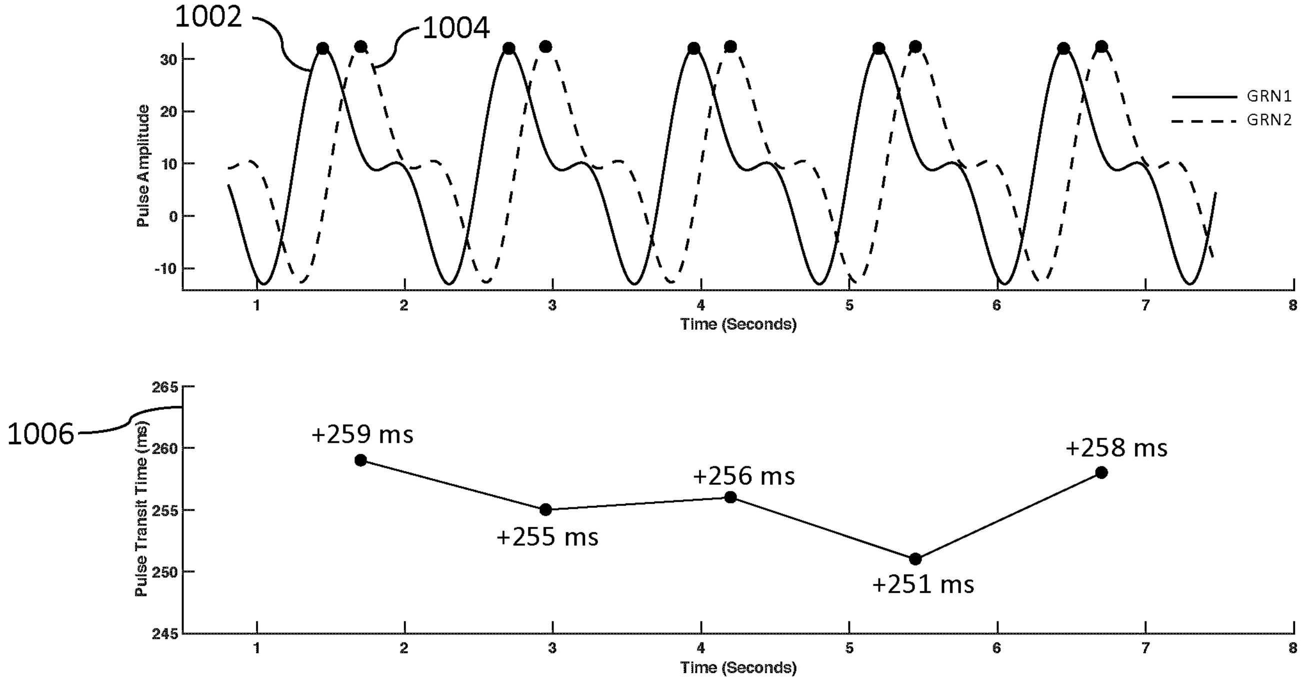

FIG. 10B

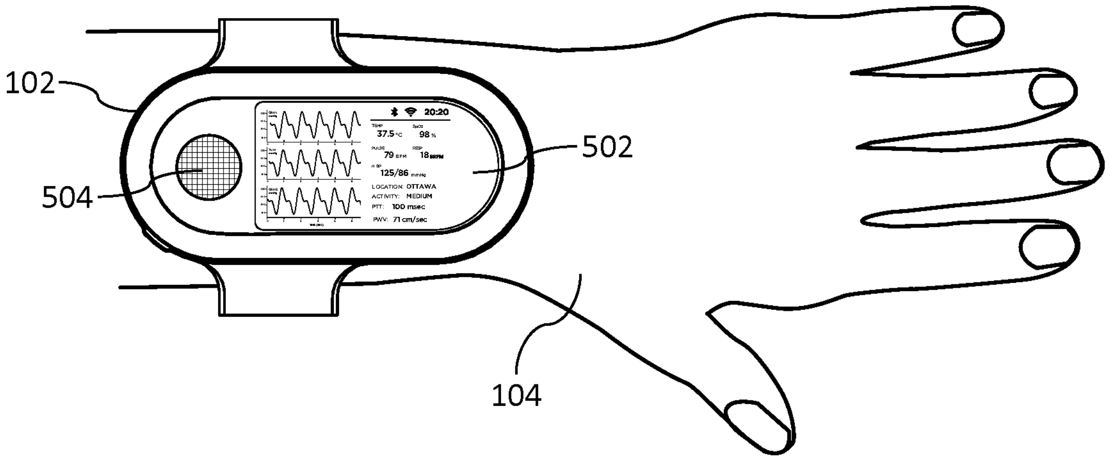

FIG. 11A

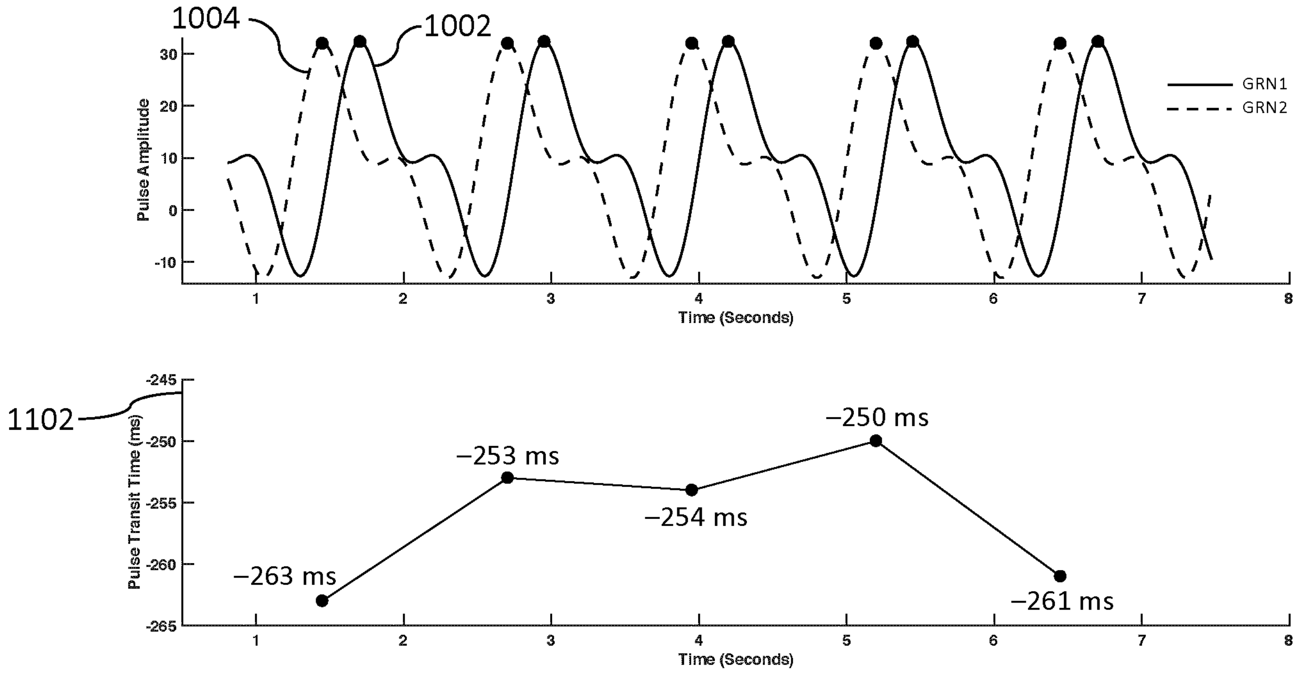

FIG. 11B

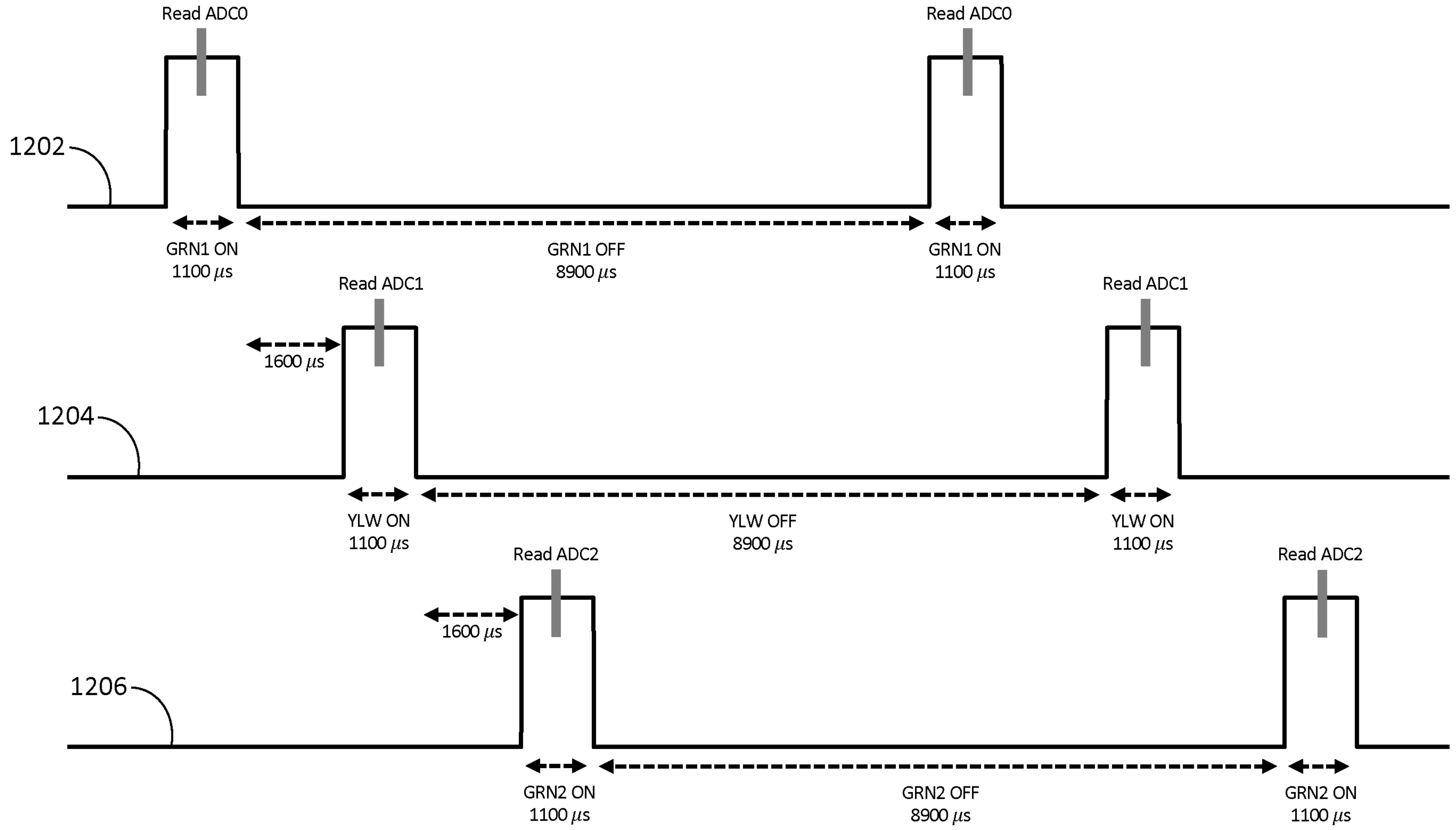
Read ADC0
Read ADC0
1202
GRN1 ON
1100 μs
GRN1 OFF
8900 μs
GRN1 ON
1100 μs
Read ADC1
Read ADC1
1600 μs
1204
YLW ON
1100 μs
YLW OFF
8900 μs
YLW ON
1100 μs
Read ADC2
Read ADC2
1600 μs
1206
GRN2 ON
1100 μs
GRN2 OFF
8900 μs
GRN2 ON
1100 μs

FIG. 12

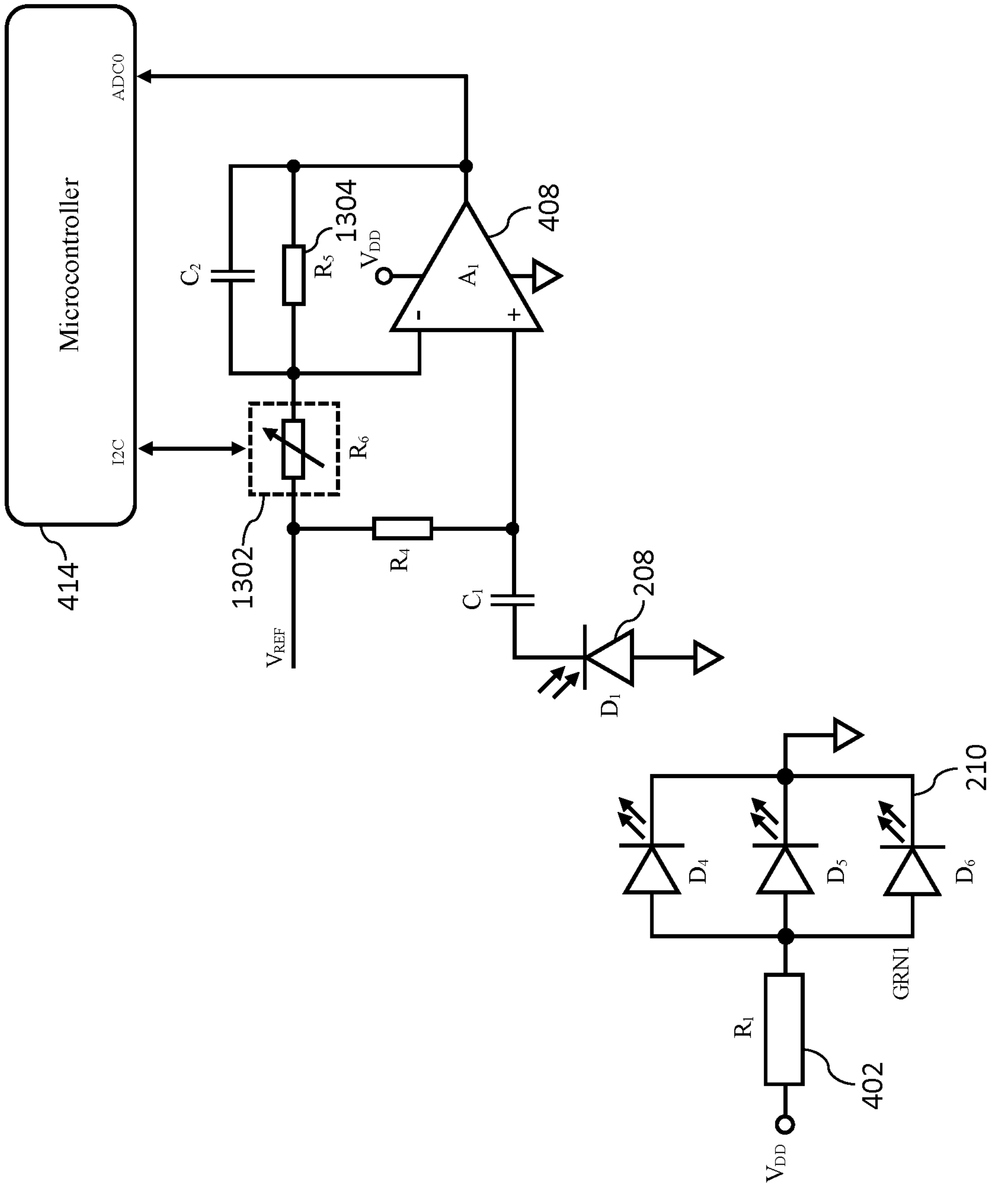
Microcontroller
ADC0
I2C
414
1302
1304
408
C_2
R_5
V_{DD}
A_1
-
+
R_6
R_4
C_1
208
D_1
V_{REF}
D_4
D_5
D_6
210
GRN1
R_1
402
V_{DD}

FIG. 13

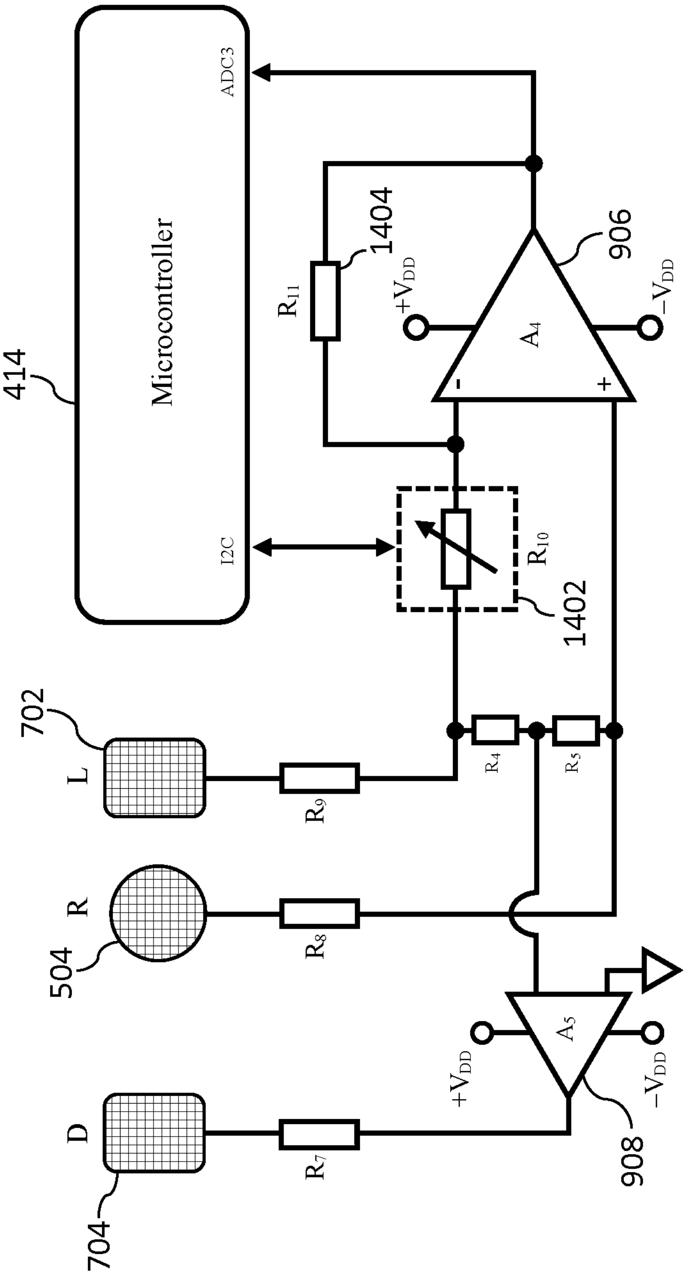
414
Microcontroller
ADC3
I2C
R11
1404
+VDD
A4
906
–VDD
-
+
R10
1402
702
L
R9
R4
R5
R
504
R8
A5
+VDD
–VDD
908
D
R7
704

FIG. 14

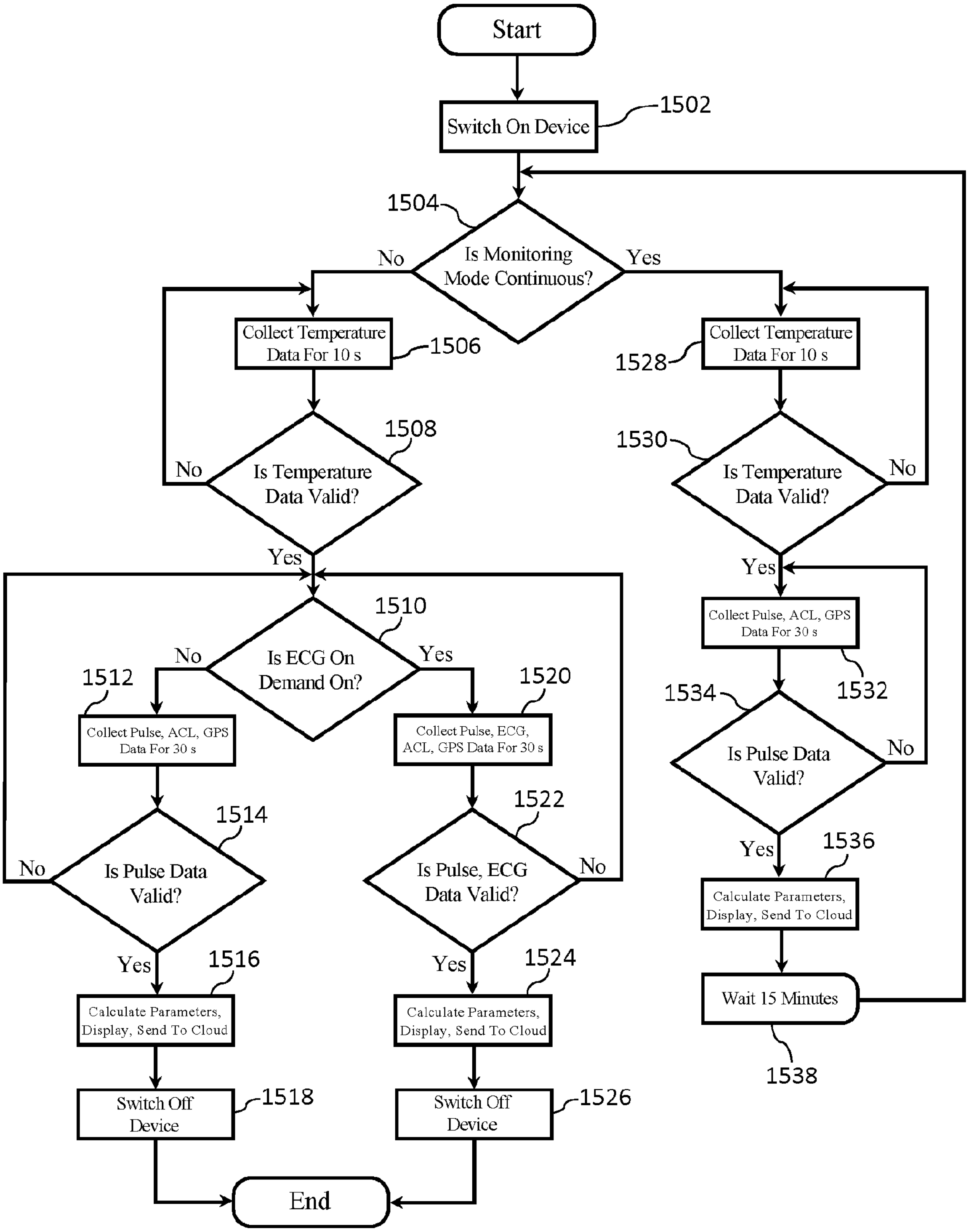
Start
Switch On Device
1502
1504
Is Monitoring Mode Continuous?
No
Yes
Collect Temperature Data For 10 s
1506
Collect Temperature Data For 10 s
1528
1508
Is Temperature Data Valid?
No
Yes
1530
Is Temperature Data Valid?
No
Yes
1510
Is ECG On Demand On?
No
Yes
1512
Collect Pulse, ACL, GPS Data For 30 s
1520
Collect Pulse, ECG, ACL, GPS Data For 30 s
Collect Pulse, ACL, GPS Data For 30 s
1532
1534
Is Pulse Data Valid?
No
Yes
1514
Is Pulse Data Valid?
No
Yes
1522
Is Pulse, ECG Data Valid?
No
Yes
1536
Calculate Parameters, Display, Send To Cloud
1516
Calculate Parameters, Display, Send To Cloud
1524
Calculate Parameters, Display, Send To Cloud
Wait 15 Minutes
1538
Switch Off Device
1518
Switch Off Device
1526
End

FIG. 15

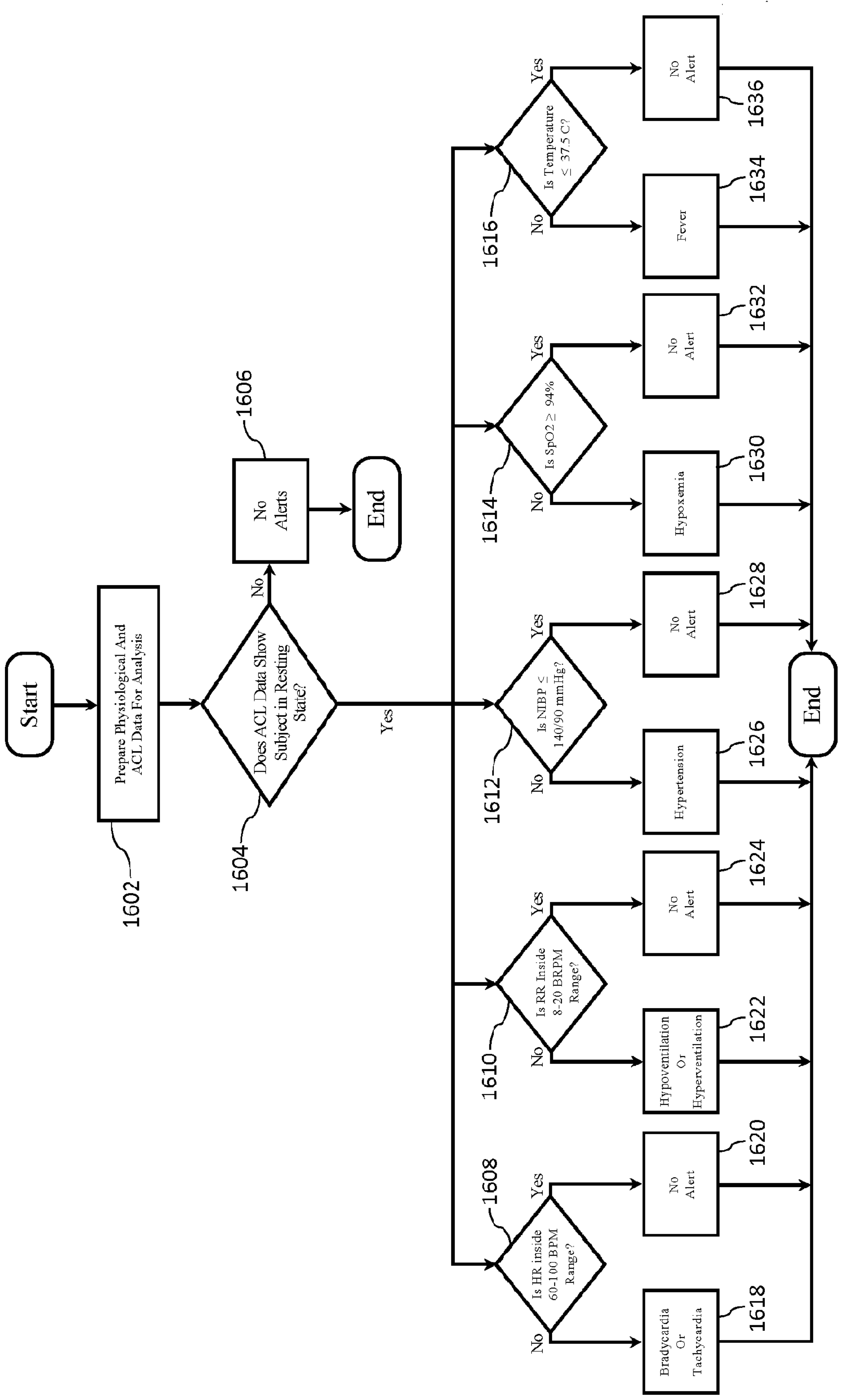
Start
Prepare Physiological And ACL Data For Analysis
1602
Does ACL Data Show Subject in Resting State?
1604
No
No Alerts
1606
End
Yes
Is HR inside 60-100 BPM Range?
1608
Yes
No
Bradycardia Or Tachycardia
1618
No Alert
1620
Is RR Inside 8-20 BRPM Range?
1610
Yes
No
Hypoventilation Or Hyperventilation
1622
No Alert
1624
Is NIBP ≤ 140/90 mmHg?
1612
Yes
No
Hypertension
1626
No Alert
1628
Is SpO2 ≥ 94%
1614
Yes
No
Hypoxemia
1630
No Alert
1632
Is Temperature ≤ 37.5 C?
1616
Yes
No
Fever
1634
No Alert
1636
End

FIG. 16

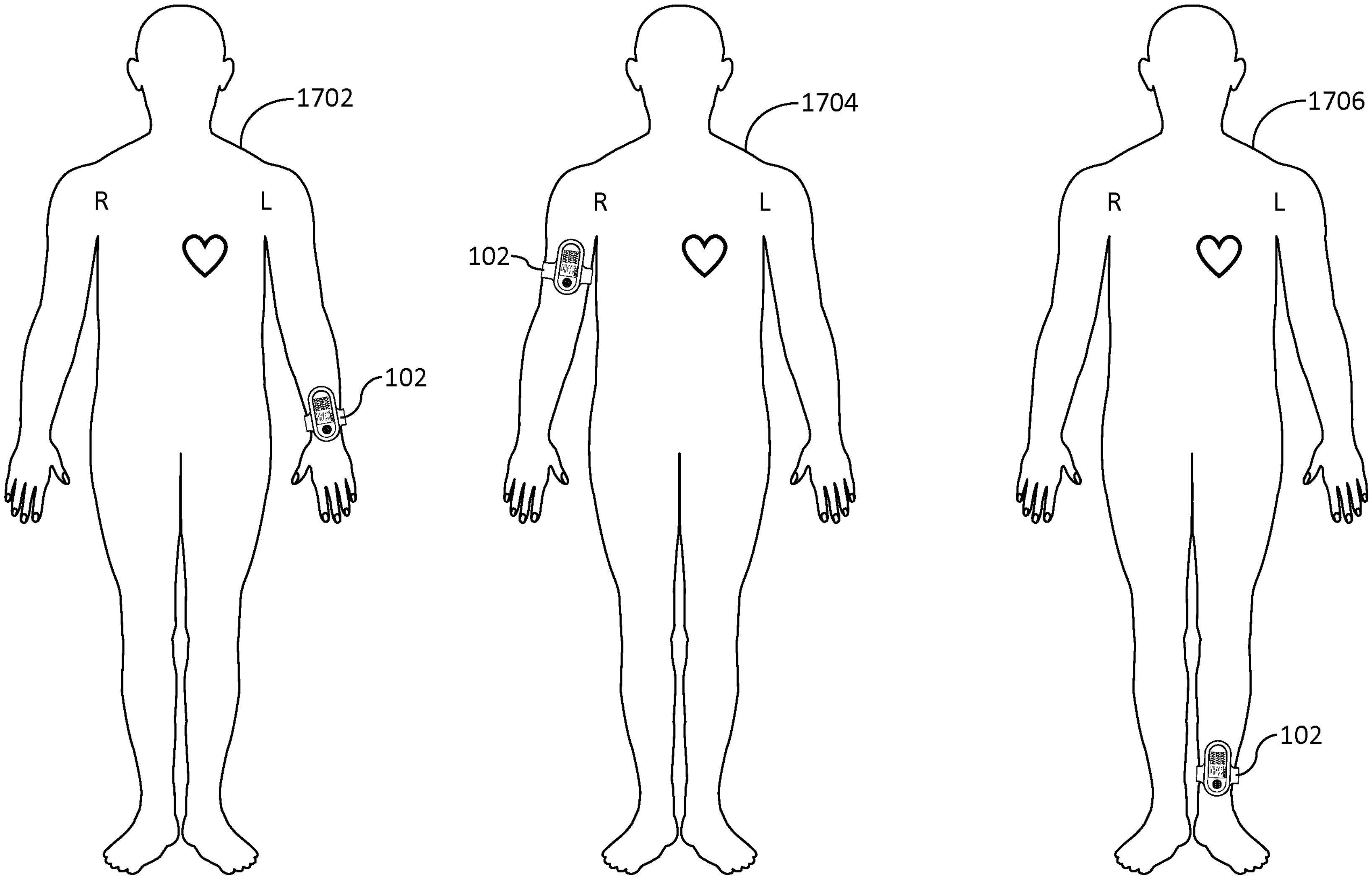

FIG. 17

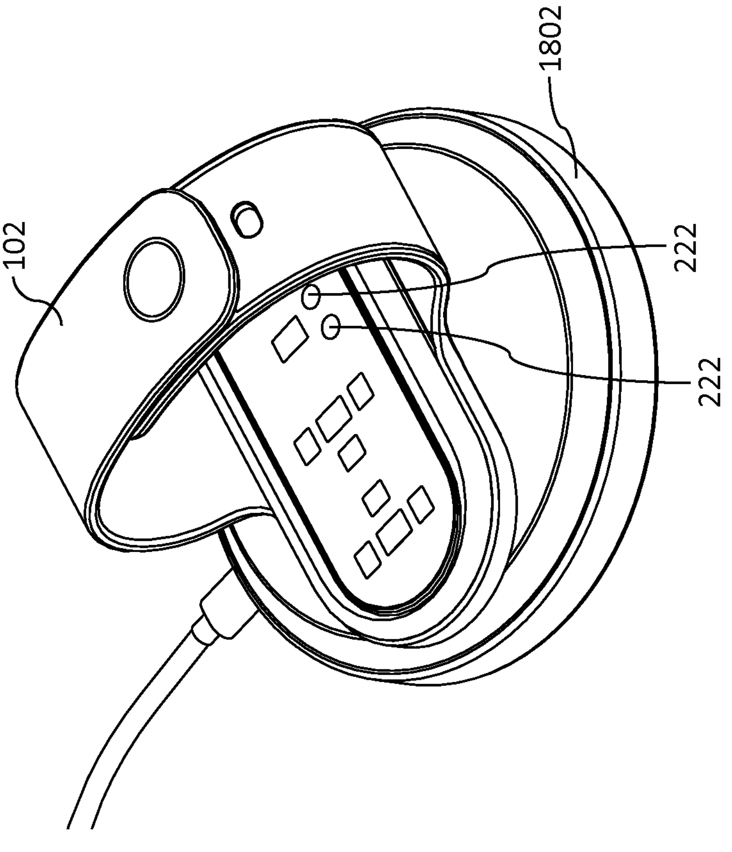

FIG. 18A

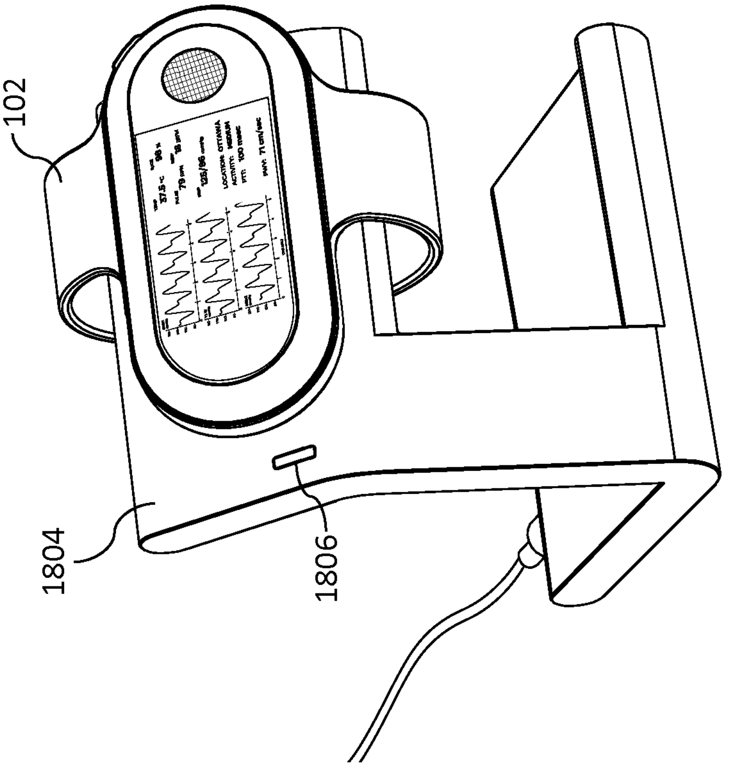

FIG. 18B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2021/050294

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **A61B 5/00** (2006.01) , ***A44C 5/00*** (2006.01) , ***A61B 5/01*** (2006.01) , ***A61B 5/02*** (2006.01) ,
A61B 5/021 (2006.01) , ***A61B 5/024*** (2006.01) (more IPCs on the last page)

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: **A61B 5/00** (2006.01) , ***A44C 5/00*** (2006.01) , ***A61B 5/01*** (2006.01) , ***A61B 5/02*** (2006.01) ,
A61B 5/021 (2006.01) , ***A61B 5/024*** (2006.01) (more IPCs on the last page)

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

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
KWIC: smart, wristband, biosensor, microcontroller, multiparameter, vital, LED
Databases: CPD, Questel Orbit, Google Patents

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US20190117083(A1) 25 April 2019 (25 -04-2019) by Wang et al. ** see abstract, entire application**	1 2-40
A	US2018106897(A1) 19 April 2018 (19-04-2018) by Redmond et al. ** see abstract, entire application**	2-40

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

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
"D"	document cited by the applicant in the international application	"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
"E"	earlier application or patent but published on or after the international filing date	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search
18 May 2021 (18-05-2021)

Date of mailing of the international search report
05 June 2021 (05-06-2021)

Name and mailing address of the ISA/CA
Canadian Intellectual Property Office
Place du Portage I, C114 - 1st Floor, Box PCT
50 Victoria Street
Gatineau, Quebec K1A 0C9
Facsimile No.: 819-953-2476

Authorized officer

Karen Oprea (819) 639-8255

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2021/050294

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
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