



- (51) **International Patent Classification:**
A61B 5/02 (2006.01) A61B 5/0402 (2006.01)
- (21) **International Application Number:**
PCT/US20 13/049667
- (22) **International Filing Date:**
9 July 2013 (09.07.2013)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
61/669,474 9 July 2012 (09.07.2012) US
61/733,865 5 December 2012 (05.12.2012) US
61/733,871 5 December 2012 (05.12.2012) US
- (72) **Inventor; and**
- (71) **Applicant : CRONE, William E.** [US/US]; 7500 329th Avenue SE, Fall City, Washington 98024 (US).
- (74) **Agents: GRAY, JR., Richard O.** et al; GRAYBEAL JACKSON LLP, 400 - 108th Avenue NE, Suite 700, Bellevue, Washington 98004 (US).
- (81) **Designated States** (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM,

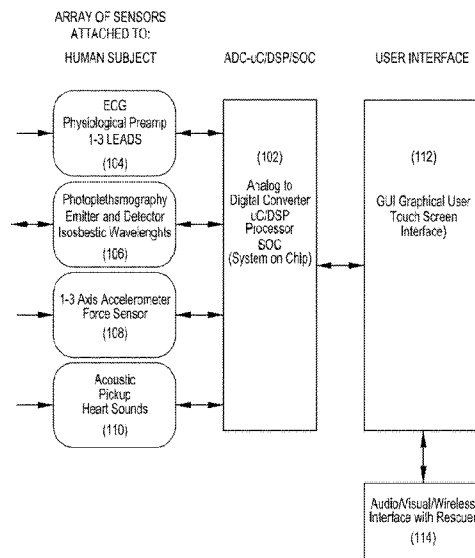
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:
— with international search report (Art. 21(3))

(54) **Title:** PERFUSION DETECTION SYSTEM

FIG. 5 HW/SW/FW SYSTEM (100)



(57) **Abstract:** According to some embodiments, a system for detecting a perfusion index of a cardiac pulse includes a first sensor that senses a first physiological or environmental parameter of a human patient core, a second sensor that senses a second physiological or environmental parameter of the human patient core, a processor that, responsive to the first and second sensed parameters, determines a perfusion index ranging from 0 to 10 that reflects inadequate, marginal, or adequate blood perfusion to the core of the human patient torso, and an indicator that provides a discernible indication of the perfusion index. A method of detecting a perfusion index of a cardiac pulse responsive to sensing first and second physiological or environmental parameters of a human patient core is also disclosed.

WO 2014/011599 A1

PERFUSION DETECTION SYSTEMClaim Of Priority

[1] The present application claims the benefit of U.S. Provisional Patent Applications Serial No. 61/669,474, filed July 9, 2012; Serial No. **61/733,865**, filed December 5, 2012; and Serial No. **61/733,871**, filed December 5, 2012; all of which applications are incorporated herein by reference **in** their entireties.

Background

[2] The ability to determine the existence of sufficient **oxygenated** blood to the head and neck to keep a patient from suffering permanent cognitive damage is of key importance in **multiple** situations. EMS (Emergency Medical Services) professionals and primary care physicians have long sought **for** a device that can quickly assess the existence of a perfusion pulse to **assist** them in determining the proper immediate action necessary for the preservation of cognitive neurological function,

[3] In addition the ability **to** have physiological feedback while performing emergency CPR is also of key importance **to** insure the highest probability of the patient being **neurologically intact** after various **types of cardiopulmonary** events.

[4] As **an** example, the ability to determine that a human **subject is in PEA (Pulseless Electrical Activity) is key** as the method of treatment may be different than if the patient was determined to be in Ventricular Fibrillation.

[5] The number of people worldwide that are impacted by sudden cardiac death (SCD) ranges from the hundreds of thousands per year to numbers that exceed 1 million depending on the literature cited. Embodiments described herein and associated methodology to achieve the above performance is aimed at assisting the lay person, the EMS professional and the entire medical community in determining the immediate and long term assurance of adequate perfusion.

[6] Reliable perfusion detection, the ability to determine that there is a "pulse" is difficult and has been attempted by numerous colleagues. The problem relates to determining in the presence of motion, various pharmacologics, and external environmental contributors, when the patient has an adequate pulse to keep them alive without cognitive damage until medical professionals arrive. Embodiments described herein address these and other issues by providing a solution through use of physiological parameters and additional body worn sensors.

Summary

17) Embodiments use multiple physiological and non physiological sensors to determine the presence of a pulse. A Photoplethysmography waveform describes the time related absorption of light associated with Oxy and DeOxy hemoglobin. Analysis of the photoplethysmography contour may be evaluated to assist in the indirect assessment of stroke volume and cardiac output. In addition, usage of a three axis accelerometer/force sensor, acoustics, as for example, particular heart sounds associated with the closure of the aortic valve S2, and the ECG (electrocardiogram) may be utilized to determine an adequate

perfusion pulse. The **parameter** that **is** presented **is called the** 'perfusion index'. The **perfusion** index is a numeric value that relates the degree **of** perfusion **to various organs in the** body. The **higher** the number the higher the **perfusion** to the vital organs in the body. The number is relative and values range from 0 to 10. The level deemed 'adequate' to prevent neurological damage to the patient is determined by a preset value determined by numerous clinical trials **on** various patients with various life threatening conditions.

[8] Usage of a single physiological parameter such as photoplethsmography is prone to motion **sensitivity**, application pressure, and sensor location.

[9] Embodiments described **herein** utilise multiple physiological parameters to determine the existence of a perfusion pulse using the core homeostasis of the **human**. **No** peripheral locations are utilized. While peripheral locations **could** be utilized **they** are more **prone to** errors **associated with** peripheral vascular disease, shock, and other conditions where the body has decided to shut down the peripheral system in order **to maintain** the core. Multiple parameters **are** utilized **to** reduce the typical confounding variables associated with accurate detection of a pulse, such as motion, pressure, acceleration/force, and location,

[10] To determine that a perfusion pulse exists to the brain it is necessary to determine that **there** is sufficient **Stroke** volume **to move** oxygenated blood from the left ventricle of the heart muscle to the head within a specified period of time. **To** do this a trigger may start a time clock to determine **how** many ~~milli~~seconds after a compression (Heart systole or external chest **compression**) (CPR-Cardiopulmonary Resuscitation) the signal arrives **at** a location in the core of the human

subject. To do this the trigger to start the time can be the **QRS** complex of the ECG (electrocardiogram) if it is present, or it could be a signal from an accelerometer/force sensor (1,2, or 3 axis) which indicates the force of the heart when contracting {systolic period}, or it could be a signal associated **with** external chest compression or heart sounds associated with the aortic valve closing (S2 sound). The evaluation of the photoplethsmography contour itself may be utilized to assist in the determination of the **cardiac** output/ stroke volume. This is important as during manual heart compression (CPR) and in hemodynamically compromised patients the contour of the **photoplethsmography** waveform will be quite different than in an alert patient. **Prior to evaluating** the contour of the **waveform** the waveform is preferably normalised. The accelerometer/force sensor can be located in a multiple of places on the human torso but are typically placed on the sternum during CPR, on the head, or in a **wearable** band placed below the nipples on the chest. If the ECG is not present, then the accelerometer/force sensor and/or heart sounds can be utilized to determine when the heart aortic valve opens to eject **blood from** the left ventricle. The time taken from the time the aortic valve opens to the time the photoplethsmography pulse **arrives** at a predefined location on the core of the human subject can be utilized. The pulse is defined as an increased volume of blood associated with the stroke **volume** of the patient's heart. In cases where heart sounds are not detectable and the **ECG** is not present, the accelerometer/force sensor that detects motion associated with CPR can be used as the timing trigger.

[11] The calculation of the timing between the accelerometer/force sensor signal and/or the ECG signal and the

arrival of the photoplethysmography signal, may be modified using contour analysis of the photoplethysmography normalized waveform.

[12] The pre-ejection time, the time period between the QRS complex and the time the blood is ejected through the aorta can

5 be measured in those cases where heart sounds are available, and

then placed into a regression formula along with the time from the detected QRS complex to the arrival of the normalized

contour modified amplitude photoplethysmography detection point at a prescribed location on the human torso. The detection point

10 of the photoplethysmography signal may be adjusted as a function

of the contour of the photoplethysmography waveform and its first derivative. The resultant output of the regression formula is

correlated to the valid range of time periods and a decision is made as to whether the timing is consistent with adequate

15 perfusion. A "perfusion index" is calculated and if the time

period is beyond, longer than the lower time limit, the preset value the system activates an alarm One of the key benefits of

this perfusion system is the use of at least two physiological parameters to determine an adequate perfusion index and time

20 frequency relationship between them. While this perfusion

detection system has the highest specificity and sensitivity

when used with the ECG, an Accelerometer/force sensor,

Photoplethysmography contour, and acoustic sensors, determination of the perfusion index can be achieved with as little as two

25 physiological sensors, albeit with lower sensitivity and

specificity that if all sensors were available .

[13] Hence, according to some embodiments, a system for detecting a perfusion index of a cardiac pulse comprises

a first sensor that senses a first physiological or

30 environmental parameter of a human patient core, a second sensor

that senses a second physiological or environmental parameter of

the human patient core, a processor that, responsive to the first and second sensed parameters, determines a perfusion index ranging from 0 to 10 that reflects inadequate, marginal, or adequate blood perfusion to the core of the human patient torso, and an indicator that provides a discernible indication of the perfusion index .

[14] The first and second sensors may include at least one of an accelerometer/ force sensor, photoplethysmography sensor, an ECG sensor, one or more leads, a one to three axis accelerometer/force sensor, and an S1/S2 heart sound sensor. The system may further include a cardiac arrest detector. The system may still further include a detector that detects the existence of PEA {Pulseless electrical activity} .

[15] The processor may be programmable to determine the presence of atrial fibrillation for those patients who have low EF (Ejection Fraction) .

[16] According to other embodiments, a method of detecting a perfusion index of a cardiac pulse comprises sensing a first physiological or environmental parameter of a human patient core, sensing a second physiological or environmental parameter of the human patient core, determining, responsive to the first and second sensed parameters, a perfusion index ranging from 0 to 10 that reflects inadequate, marginal, or adequate blood perfusion to the core of the human patient torso, and providing a discernible indication of the perfusion index.

Brief Description Of The Drawings

[17] FIG. 1 is a graph showing an idealized response of an accelerometer/ force sensor or force sensor to the recoil
5 associated with the forces of the heart .

FIG. 2 is a graph showing an idealized ECG waveform showing the QRS **complex** used to form a **trigger** in the timing described in this application..

[18] FIG. 3 is a graph showing idealized **heart** sounds heard
10 through a stethoscope, microphone, or other acoustic devices. The S1 S2 sounds are associated with various valves closing during the cardiac cycle, the 'lufo dub' as it is often referred to literature.

[19] FIG. 4 is a graph of an inverted photoplethsmography
15 signal **taken** at one of many isosbestic wavelengths. This waveform would look approximately the same if taken at one of the many IR wavelengths often used when determining SpO2 ..

[20] FIG. 5 is a block diagram of a system for **practicing**
embodiments of the invention.

20 [21] FIG. 6 is a flow chart describing the steps which may be taken **by** the system of FIG. 5 to determine if a **person** has adequate perfusion to prevent neurological damage to the brain and other organs in the body.

Detailed Description

25 [22] FIGS. 1-4 are a time combined set of waveforms showing the various sensors and associated **waveforms** that may be utilized in practicing the invention in its various embodiments

to advantage. FIG. 1 is an idealized response of an accelerometer/force sensor or force sensor to the recoil associated with the forces of the heart. FIG. 2 is an idealized ECG waveform showing the QRS complex used to form a trigger in the timing described herein. FIG. 3 are idealized heart sounds heard through a stethoscope, microphone, or other acoustic devices. The S1 S2 sounds are associated with various valves closing during the cardiac cycle, the 'lub dub' as it is often referred to literature. FIG. 4 shows an inverted photoplethsmography signal taken at one of many isesbestic wavelengths. This waveform would look approximately the same if taken at one of the many IR wavelengths often used when determining SpO2.

[23] Referring now to FIG. 5, it is a block diagram of a system according to embodiments of the invention. The system 100 generally includes a processor or microcontroller (uC) 102 and various peripheral circuits or units to generate data or display data and/or notifications to an operator. The uC 102 is arranged to operate according to operating instructions stored in memory. The operating instructions permit the uC to perform analog to digital conversion, processing of data to determine the various parameters disclosed herein, and to function as a wireless transceiver.

[24] The various circuits or units include a physiological preamp with 1 to 3 leads 104, a photoplethsmography emitter and detector 106, a 1-3 axis accelerometer and force sensor 108, and an acoustic sensor 110 to pickup heart sounds. The circuits and units further include a graphic user touch screen interface 112 and an audio/visual wireless interface. As will be seen, programming the uC in various ways permit the system to function

as a perfusion detector, a tool to assist the operator in performing **CPR**, an atrial fibrillation detector., a detector **for** pulseless electrical activity (PEA), a detector for low ejection fraction, and to determine Asystole. **Further**, the **uC** 102 may **be** 5 programmed with parameter ranges to enable various required comparisons to determine if various parameters are within certain ranges. Other functions of the **uC** and of the system 100 will become apparent herein after.

[25] Referring now to the flow chart of FIG. 6, upon Power 10 On, the **uC** of the system **performs** some rapid self tests and then the process proceeds down the flow chart.

[26] The first determination made in decision block 2 is **if** there an ECG Signal such that an **R** wave can be detected. This processing is done **by** sampling the surface ECG at one or **more** 15 locations **on** the core of the human subject. This location could be the forehead, the chest, or other locations such as the common 'limb leads' used as in the case **of** a standard single, 3, 5, or 12 lead ECG.

[27] The ECG is sampled with sufficient bandwidth to allow 20 for the detection of the QRS of the ECG waveform even in the presence of an internal or external pacemaker. The method used to **detect** the QRS may consist in part of digital filtering of the ECG to reduce the signal levels of the P wave, T wave, trifoelectric interference, motion, and various other external 25 confounding variables. After analog filtering and **digitization** of the ECG waveform, digital adaptive **filters** along with **Wavelet** transformations are used to determine the QRS location in the presence of the remaining **confounders** . **Environmental** noise, **motion, including CPR, and RFI** {Radio Frequency

Interference) /EMI (**Electromagnetic** Interference) are some **typical** examples.

[28] If the decision in decision block 2 is **NO** (10) then the process proceeds to decision block 11 where it is determined
5 **if CPR is** being performed. By **examining** the output of the three **axis** accelerometer /force sensor the rhythmic pattern of CPR can be detected. The method used for this determination may utilise Wavelet transformations and Gabor Spectrograms to extract the time/frequency signature of CPR in the presence of head and
10 torso movement associated with CPR.

[29] **If it is** determined that no CPR is detected., then, in accordance with activity block 17, feedback is provided to the rescuer through the decision matrix of the uC (microcontroller) that no CPR nor perfusion has been detected and to start CPR.
15 The process the returns.

[303] If CPR **was** detected in decision block 11, then the **system,** in accordance **with** decision block 13 evaluates the presence **of** a photoplethsmography signal and determines if the change in volume **measured** by the **photolethstnography** system is
20 consistent in **time with** the QRS complex **to represent sufficient** perfusion to sustain the patient. If there is a photoplethsmography signal available, then the process proceeds **to activity** block 15 where the timing between the CPR compression and the arrival of the increased blood volume at the
25 photoplethsmography site is performed. In conjunction with the **accelerometer /force** sensor detection of the Chest compression, the detection of the S1/S2 heart sounds could be utilized **in** conjunction with or in lieu of the **accelerometer/ force** sensor signature. A photoplethsmography signal at various wavelengths
30 can be used but in this **system** we choose to use isosbestic

wavelengths to remove any confounding variables associated with the level of **oxy/deoxy** hemoglobin levels associated with the patient's blood. By examining the photoplethsmography signal and its contour and **looking** for the reduction in signal level associated **with** the **largest** volume of **blood that** passes the isosbestic light source and corresponding optical receiver array, a determination can be made of the time taken to move the large volume of blood **from** the Left ventricle to the position of the sensor, the change in volume associated with Left

5

10 Ventricular contraction. After securing this time value a decision is made as to whether the **arrival** of the large **volume** of blood is **within** a preset value range. This information is then used to provide feedback to the rescuer as to the adequacy of their compressions. If the time period calculated is long the

15 rescuer is encouraged to push harder and faster. The **determination** of whether the depth is inadequate and/or the compression rate **is** too slow **is** determined by calculating the compression rate using the 1-3 axis accelerometer. IF the time period is short then the feedback that is provided is that the

20 **CPR is** being **performed** well.

[31] If the **Photoplethsmography signal**, the **increased** blood volume time arrival at the photoplethsmography site is too long, then the decision of decision block 13 **is NO** and the existence of an **S1/S2** sound is evaluated. This is performed in decision

25 block 20 **where** an S1/S2 sound is determined **to exist**. Then **the** required time interval **between** the S1/S2 sound and the **arrival** of the increased blood volume is calculated in activity block 15. If no S1/S2 sound is found in decision block 20, then, in activity block 22 feedback **is** provided to the rescuer that **no**

30 adequate perfusion is being found and that CPR needs to be

initiated or compression **depth/rate needs to increase**. If the
time window calculated using the **S1/S2** sound and the arrival of
the increased blood **volume** passing **through** the optical **sensors**
are **within** the specified range, then the decision in decision
5 **block 20 is YES {18} and the** corresponding perfusion index is
calculated and fed back to the rescuer in activity block 19, **The**
perfusion index in this decision sequence is determined using
the detection of a **CPR Compression** and the time to detection of
the increase in blood volume at the optical sensor array
10 position,

[32] If in decision block 22 a QRS complex is detected,
then the process proceeds to decision block 4 to determine if a
photoplethstnography signal **representing increased blood volume**
within a **specified time window from the QRS complex** of the SCG
15 is present. The detection of increased blood volume may be
detected by the decrease in optical light detected at the
optical receiver array due to the increase in absorption of the
specific wavelength of light associated with blood. The
derivative of the optical waveform is **performed** to include in
20 the decision **process** the **contour** of the photoplethsmography
waveform. If the decision **of** decision block 4 is YES, then the
existence of **S1/S2** sounds representing closure of the atrial
ventricular valves and the aortic valve are evaluated in
decision block 6. If the answer to this decision in decision
25 block 6 is YES, then, the time sequence from the QRS complex and
the S1/S2 sounds and **from** the S1/S2 sounds to the
Photoplethsmography signal is evaluated in decision block 8 and
the **corresponding** perfusion index is calculated. If the time
between the S1/S2 sounds or the QRS complex is outside of
30 bounds (a NO **answer** in decision block 8, then the rescuer is

told to **start CPR** in activity block 41. If the **perfusion** calculation shows that the perfusion index is within specified range the decision in decision block 3 is YES, the rescuer- is told that the patient has a viable perfusion index and provided with a numeric value for the displayed number. The process then returns .

[33] If the decision in decision block 6 is that there is no S1/S2 sound, the existence of a Ballistocardiogram is determined in decision block 34. Here, the HI curve and/or the U K curve can be **determined** to exist or **not** exist and can potentially be used to determine the perfusion index. The method for **determining the HI curve of the Ballistocardiogram** may use various descriptors including template matching of the HI, IJK curves, their derivatives, force sensor; the force of the contraction of the **Left Ventricular ballistocardiogram, wavelet** transforms and the Gabor spectrogram. If the Ballistocardiogram **exists**, in particular **the HI and** or **IJK curves**, then the process proceeds to activity block 36 where the perfusion index can be calculated by looking at the time period **between** the HI, U K curves of the **Ballistocardiogram and** the arrival of the increased blood volume at the **photoplethsmography** optical **receiver** site. The process then proceeds to decision block 37 to determine if the time period is within the required **time** window to represent a viable perfusion index. If it is, then the rescuer is informed of the perfusion index value (38, and the process returns. If the time period is **HOT** within the required **time** window, the rescuer is told to start or enhance/start CPR and the process returns.

[34] If in decision block 34 no balistocardiogram signal is found, then, in decision block 43 it is determined if **there** is a

three axis **accelerometer/force** sensor signal and is analyzed for a signature that is rhythmic in nature to determine if it can be utilized as a time marker. Again utilization of the **signature** of rhythmic CPR may be utilized along with Wavelet transforms and the Gabor spectrogram to capture the **HI, IJK** curves of the Ballistocardiogram as compared to other confounding variables.

[35] Please note that during CPR the nature of the **HI, IJK curves** will change. The **HI, IJK** curves will not have the same morphology during **manual** CPR than during regular **NSR (Normal Sinus Rhythm)**. The **coefficients** of the formula will account for the morphological differences.

[36] If the **answer** in decision block 43 is YES, the perfusion index is analyzed in activity block 45 and then a **determination** is made in decision block 46 if the analysis shows the perfusion index to be **within** bounds to represent a perfusion pulse. If the calculation shows that the perfusion index is within bounds, then the rescuer is informed and the **process** returns. If the result is not within bounds, the rescuer is prompted to start CPR in activity block 50.

[37] It should **be** noted that at decision block 43, where an **accelerometer/ force** sensor signal that is rhythmic in nature is not found while a valid photoplethsmography signal is available, an indication of a **hardware** failure is so noted in activity block 93,

[38] Returning to decision block 4, if in decision block 4 it is determined that there is **no photoplethsmography** signal that represents the required increase in blood volume within the specified window after ventricular systole a couple of unique additional decisions are made. A check **is** made to determine if

the **photoplethmography** signal is 'flat' (asystole) given **no** accelerometer/force sensor signals. If the answer to this **question "Is there a photoplethmography signal"** in decision block 24 is **NO**, then a final check to see if there **is** an S2 heart **sound is** checked in decision block 28. **If not**, then **PEA** is declared to the rescuer in activity block 32. If an S2 sound is found, then a **HW** failure is flagged and the rescuer alerted in activity block 30. The processor will self check on a periodic nature to see if the fault has been cleared,

10 [393 If in decision block 24 it is decided that there is a **photoplethmography** signal but one that fails the criteria defined in decision block 4, then the calculation of a perfusion index is initiated in activity block **26** with the full understanding that the value is out of range. This condition may **represent** Pseudo PEA and the **rescuer** is so **informed**. The process then returns.

[40] The following are exemplary technical details of how various aspects of this invention achieve the final goal of **determination** of the perfusion index.

20 [41] The ECG waveform is filtered, and the detection of the QRS complex with minimum group delay is **performed**. Evaluation of the QRS complex and **utilizing** the QRS complex as a timing trigger is done in a **repeatable** manner associated with the detection of the **QRS complex for use as a time trigger point**,

25 [42] Photoplethmography is utilized to determine the contour and arrival of the systolic blood **volume** as a result of the Left **Ventricle contraction** and ejection of the **stroke volume** of blood on a beat by beat basis. The oxy and deoxy hemoglobin in the blood absorb light in the visual and **infrared** regions 300

nra to 2500 rim wavelengths and beyond. Specified **wavelengths** are selected that are close to the iosobestic wavelengths, 569, 805 to mention a few, but any wavelength can be used where blood **hemoglobin** absorbs light. One must be careful in selecting the
5 desired **wavelength due to** environmental contamination. Water absorbs light above around 1100 nra and beyond so care must be utilized in selection of wavelengths above the Si cutoff **of** 900 nra. Water wavelengths have been utilized to assist in removing motion artifact from the receive signal in the past.

10 [43] The contour of the **photoplethsmography** signal is examined by taking the derivative of the waveform and comparing the resultant contour to that of an alert perfusion contour. A least squares comparison is done and the result of this comparison results in a specific value (s) in the polynomial
15 **regression** formula to be made,

[44] The accelerometer/ force sensor signals can from three locations: X, Y, Z, The position of the patient is **determined** along with any rhythmic pattern **of** the **accelerometer/ force** sensor consistent with desired patient status of supine when
20 being examined. In addition to any '**rhythmic** pattern' various **components** of a Ballistocardiogram are investigated, in particular the HI curve and the **U K** curves. These curves are analysed as are their first and second derivatives. This information assists **in** determining the coefficients for the
25 regression formula which has **as** its independent variable time and the y variable as the 'perfusion index', a value from 0 to 10 on the x axis.

[45] The **Ballistocardiogram** is first normalized and then the HI, **U K curves**, including first and **second** derivatives, and
30 there corresponding contours **are** evaluated and compared to known

contours associated **with normal** ventricular contractions and those associated with **CFR** and cardiovascular disease, and timing relative **to** the QRS complex **if it** is available. The **results of** this analysis determines coefficients in the polynomial used to
5 determine the Perfusion index as described above.

[46] **The heart sounds**, in **particular s1,s2** are evaluated **to** see if the stroke volume and the nature of the closing of the **atrial -ventricular** valves and the aortic valve are consistent with sufficient perfusion to cause the aortic valve to close
10 within a preset time window. The result of this analysis again modifies the coefficients in the perfusion detection polynomial.

[47] All of the above physiological /environmental sensors may be **utilized** to adjust the perfusion index polynomial to insure that the various parameters are weighted correctly when
15 applying the 'perfusion index' value.

[48] Upon power ON the SOC uC does a series of self checks including sequencing available sensors **for use in** the polynomial **that** determines **the** Perfusion Index **output**. The device preferably indicates to the rescuer to '**stand clear**' and '**not**
20 touch the patient'

[49] After a 3 second waiting period for the **accelerometer/ force** sensor signal to go to '**zero***, **if the motion** signal ceases, the uC/DSP looks at the ECG signal and determines if an **R** wave is present that meets the frequency and temporal
25 characteristics of a normally conducted R wave. If the motion signal does not cease, the processor uses **a more highly** filtered signal along with Wavelet. **Gabor spectrographs** to **separate** the **desired accelerometer/ force** sensor signal from that of motion. Usage of Wavelet transformations and Gabor spectrographs are

also used to separate the motion artifact from the desired QRS complex.

[50] If a **photoplethsmography** signal exists the algorithm determines the time between the **approximate QRS detection point** and a specific trigger point of the photo-plethsomography signal. This detection point is adjustable by the health care **provider** at the **time of** manufacture. Based on this **time window** and if the **Ballistocardiogram** detection system indicates their Ballistocardiogram exists, the HI and IJK amplitudes/contours and their first/second derivative must meet a specified amplitude and contour set of criteria. Again the results of the amplitude and contour of the **accelerometer/f orce** sensor signals determines the coefficients that are utilized in the polynomial used to determine the "perfusion index" as described above.

[513] Heart sounds are utilized, if available to determine the functioning of the atrial-ventricular valves and the aortic valve. The morphology of the S1/S2 heart sounds **are** examined to insure adequate perfusion. Here again the S1/S2 heart sounds are **analyzed** in the time frequency domain and the result of this analysis are the values chosen for the coefficients **in** the perfusion index.

[52] If heart sounds are not **heard and** if no **Ballistocardiogram/ accelerometer/f orce** sensor signals are present the **compute** engine can still **make a** decision about the presence: of a perfusion pulse if the time window between the detected QRS and the arrival of the corresponding photopleth signal is **within** a specified time window and morphology/contour indicative of a viable perfusion interval and indirect **assessment** of stroke volume exist.

[53] If an ECG is present but no photoplethsmography signal is available the compute engine looks for a Ballistocardiogram **signature to exist or a rhythmic compression** signature. If **either** of these signals are present during a **specified** time window from the detected **QRS**, then a decision can also be made about the presence of a perfusion pulse. Usage of Wavelets and the Gabor spectrograph are used in conjunction with **template** matching associated with the signature of the accelerometer/force sensor **to** determine if a **rhythmic** compression is occurring,

[54] If no QRS is detected the compute engine listens for S1/S2 heart sounds and then examines the presence of a photoplethsmography signal within a specified time of the S1/S2 heart sounds. **IF** no **photopleth** signal exists as well as no detected **QRS** or Ballistocardiogram **HI/IJK** signatures or rhythmic accelerometer/force **sensor** signal consistent with chest compressions, **the** device determines that there is **no viable** perfusion and provides necessary **feedback to the rescuer**.

[55] If there is an accelerometer/force sensor signal that meets specified amplitude **and morphology** contours and that **are** repeatable **within a -60-150** compression **per minute** rate the device assumes that **CPR is being given** and that in the absence of a QRS that the accelerometer/force sensor signal can be utilized along with the ballistocardiogram, S1/S2 heart **sounds**, and photoplethsmography signal to **determine** the success of the CPR compressions to form a photoplethsmography signal with sufficient timing between the accelerometer/force sensor signal and the photoplethsmography signal, the S1/S2 sounds and the Ballistocardiogram signature, A decision may be made about perfusion viability without the **presence** of the

Ballistocardiogram or the **S1/S2** sound but with these additional physiological inputs the accuracy of the system can be enhanced.

[56] The **S1/S2** and presence of the **HI, U K** curves are utilized together to enhance the accuracy of the polynomial in selecting the best coefficients of the **polynomial** used to calculate the perfusion index.

[57] The system can determine with a subset of the total number of physiological and environmental parameters available as described above whether a perfusion pulse exists in the case of **PEA** (Pulseless electrical Activity), **CPR, VT/VF** and **Asystole**.

[58] **PEA** is determined by looking at the **ECG, photoplethysmography signal, the Ballistocardiogram, the accelerometer /force sensor, and the S1/S2 sounds. The ballistocardiogram and the S1/S2 sounds are not needed for a determination of PEA, These parameters enhance the decision sensitivity and specificity by being present as well. PEA is determined by the presence of a viable ECG waveform in the absence of or in the presence of low perfusion.**

[59] **Asystole** is determined by looking for the absence of a detected **QRS, the absence of a Ballistocardiogram, an S1/S2 sounds, and the absence of a photoplethysmography signature in the presence of a QRS complex.**

[60] **VT/VF** is determined by looking at the **QRS width, its morphology, its rate, its rate variability, and the presence of a Ballistocardiogram, an S1/S2 sound, and the accelerometer/ force sensor signature. Various templates of VT/VF along with Wavelet transforms and Gabor Spectrogram's are used to enhance the sensitivity and specificity of the VT/VF detection ,**

[61] The sensitivity and specificity of the detection of VT/VF is enhanced by the presence of the Ballistocardiogram and the S1/S2 sounds but these parameters are not required to make this decision.

5 [62] CPR Quality, the ability to have a perfusion pulse, is determined as a minimum by the accelerometer/ force sensor signature associated with Sternum compression and the time relationship of a photoplethsmography signal and the morphology/contour of each signal and their derivatives. During
10 CPR the motion of the chest is significant so the preprocessing of the S1/S2 heart sounds and the Ballistocardiogram can be utilized only in the condition that the signal quality meets specified signal to artifact criteria,

[63] The 'sensors' may consist of one or more locations of
15 ECG electrodes, a 1-3 axis accelerometer/force sensor, respiratory detection in the form of impedance pneumography or other means (photoplethsmography/ECG/ strain gage), photodiode emitters and corresponding photodetectors for detection of the photoplethsmography signal in one or more locations, and finally
20 acoustic pickup devices for the detection of heart sounds, in one or more locations,

[64] The ECG is digitized and the QRS is detected using a software algorithm. The detection point is usually near the J point of the ECG waveform,

25 [65] The 1 to 3 axis accelerometer/force sensor signals are digitised and have a useful bandwidth of 0.1 to 5 hertz,

[66] The photoemitters are pulsed at a high frequency and the photodiode receivers signals are then demodulated. The extracted photoplethsmography waveform associated with changes

in **signal** attenuation associated **with** the cardiac **cycle**, **is then digitized**. Prior to digitization the DC and AC components of the **photoplethsmography** signal are separated and gained **differently** prior to digitization. (AC component has a higher gain than the DC **component**). The AC component of the waveform is inverted and then its contour analyzed and through use of Wavelet transforms and the gabor spectrogram the proper timing detection point can be developed .

[67] The acoustic pickup is preprocessed by band-limiting the pickup **frequency** range, **amplifying** the signal and then digitizing the resultant signal. The contour and the output of a Wavelet transform and Gabor spectrogram are used to develop a proper select point of the S1/S2 sounds for determining the timing to be used in the polynomial for the perfusion detection algorithm. The timing between the acoustic pickup and the photoplethsmography waveform is **critical** for **accurate** assessment of the perfusion index,

[68] As may be seen from the foregoing, embodiments described and shown herein provide a system and method capable of detecting a perfusion index of a cardiac pulse using two or more physiological and environmental signals received from the human core torso. The **perfusion** index is a numeric value ranging from 0 to 10 that reflects inadequate, marginal, or adequate blood perfusion to the core of the human torso.

[69] Also described and shown is a system and method capable of detecting the perfusion of a cardiac pulse during cardiac arrest using two or more physiological and environmental signals received from the human torso and a system and method capable of detecting the existence of PEA (Pulseless electrical **activity**

[70] The **system may** utilize one **or more of the** following parameters to **determine** the presence of a perfusion index; an accelerometer/force sensor, **photoplethsmography** sensors, the **ECG**, one or more leads, a one to three axis accelerometer/force sensor, and S1/S2 **sounds of the heart**,

[71] Also shown and described is a system and method with the ability to be programmed to determine the presence of AF (atrial fibrillation) for those patients who have low EF (Ejection **Fraction**) .

[72] The system also has the ability to determine Asystole.

[73] **Also, embodiments of the** method and system may determine the proper **polynomial coefficients** for an equation that describes the perfusion index from a value range of 0 to 10 where the independent variable is time and the dependent variable is the perfusion index. The coefficients are **dynamic** and a function of the ECG, photoplethsmography waveform, the accelerometer/force sensor **waveforms**, and the acoustic S1/S2 when available.

[74] While particular embodiments of the present invention have been shown and described, modifications may be made, and it is therefore **intended** in the appended claims to cover all such changes and modifications which fall within the true spirit and scope of the invention as defined by those claims.

What is claimed is:

1. A system for detecting a perfusion index of a cardiac pulse comprising:
5 a first sensor that senses a first physiological or environmental parameter of a human patient core;
a second sensor that senses a second physiological or environmental **parameter** of the **human** patient core,
10 a processor that, responsive to the first and second sensed **parameters**, determines a perfusion index ranging from 0 to 10 that reflects inadequate, marginal, or **adequate** blood perfusion to the core of the **human** patient torso; and
an indicator that provides a discernible indication of the
15 perfusion index.
2. The **system of claim 1, wherein the first and second** sensors include at least one of an **accelerometer/force** sensor, photoplethsmography sensor, an ECG sensor, one or more leads, - a
20 one to three axis accelerometer/ force sensor, and an S1/S2 heart sound sensor .
3. The system of claim 1, further including a cardiac arrest detector .
25
4. The **system of claim 1, further including a detector** that detects the existence of PEA {Pulseless electrical activity} .

5. The **system** of claim 1, wherein the processor is programmable to determine the presence of atrial fibrillation for those patients who have low EF (Ejection Fraction) .

5 6. The **system of claim 1** further including a detector that detects a life threatening **condition** of a patient.

7. The **system** of claim 6, wherein the processor is programmable with parameter limits to allow for trigger level differences for alarms.

8. The **system of claim 6**, wherein the system is **further** arranged to determine Asystole,

15 9. **A** method of detecting a perfusion index of a cardiac pulse comprising:

sensing a first physiological or environmental parameter of a human patient core;

20 sensing a second physiological or **environmental** parameter of the human patient core ;

determining,- responsive to the first and second sensed parameters, a perfusion index ranging from 0 to 10 that reflects inadequate, marginal, or adequate blood perfusion to the core of
25 the human patient torso; and

providing a discernible indication of the perfusion index.

30

Figures 1-4 Showing Idealized Physiological Signals Recorded Using Four Different Sensors

FIG. 1 Idealized Ballistocardiogram

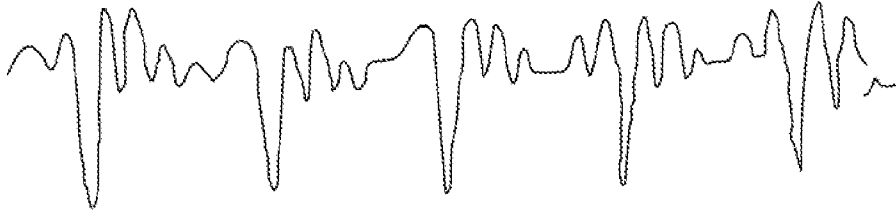


FIG. 2 Idealized ECG/EKG

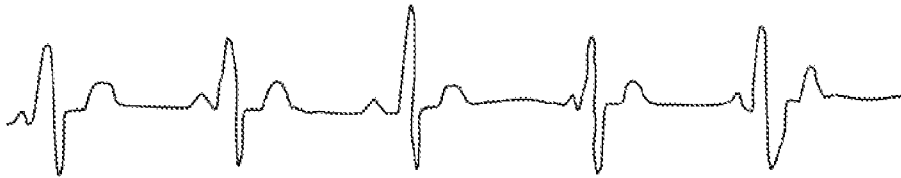


FIG. 3 S1/S2 Acoustic Heart Sounds

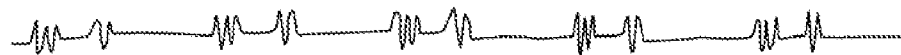


FIG. 4 Idealized Inverted Photoplethsmography Signal

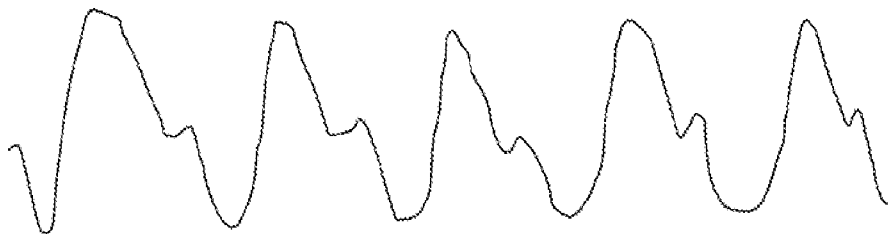


FIG. 5 HW/SW/FW SYSTEM (100)

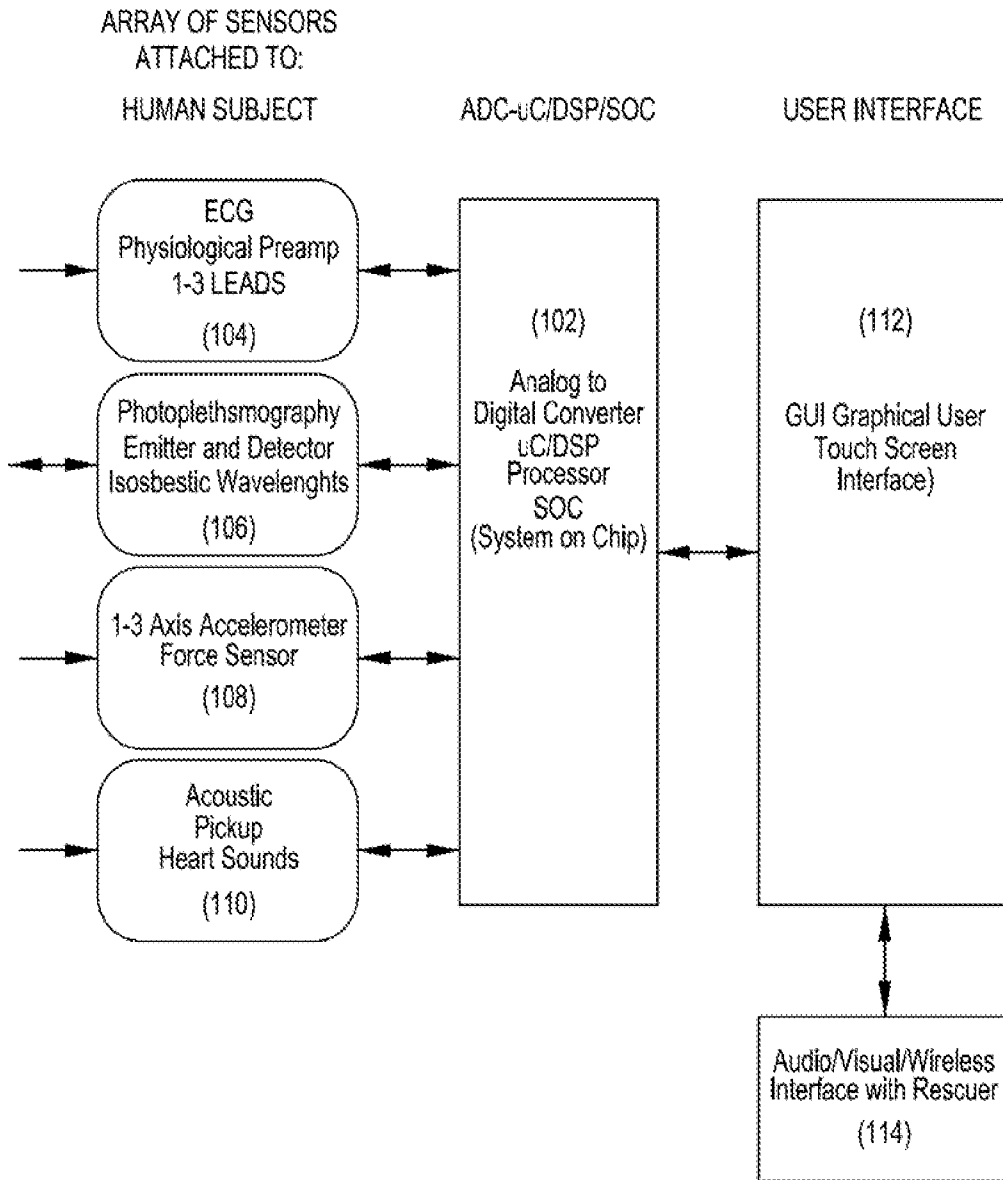


FIG. 6

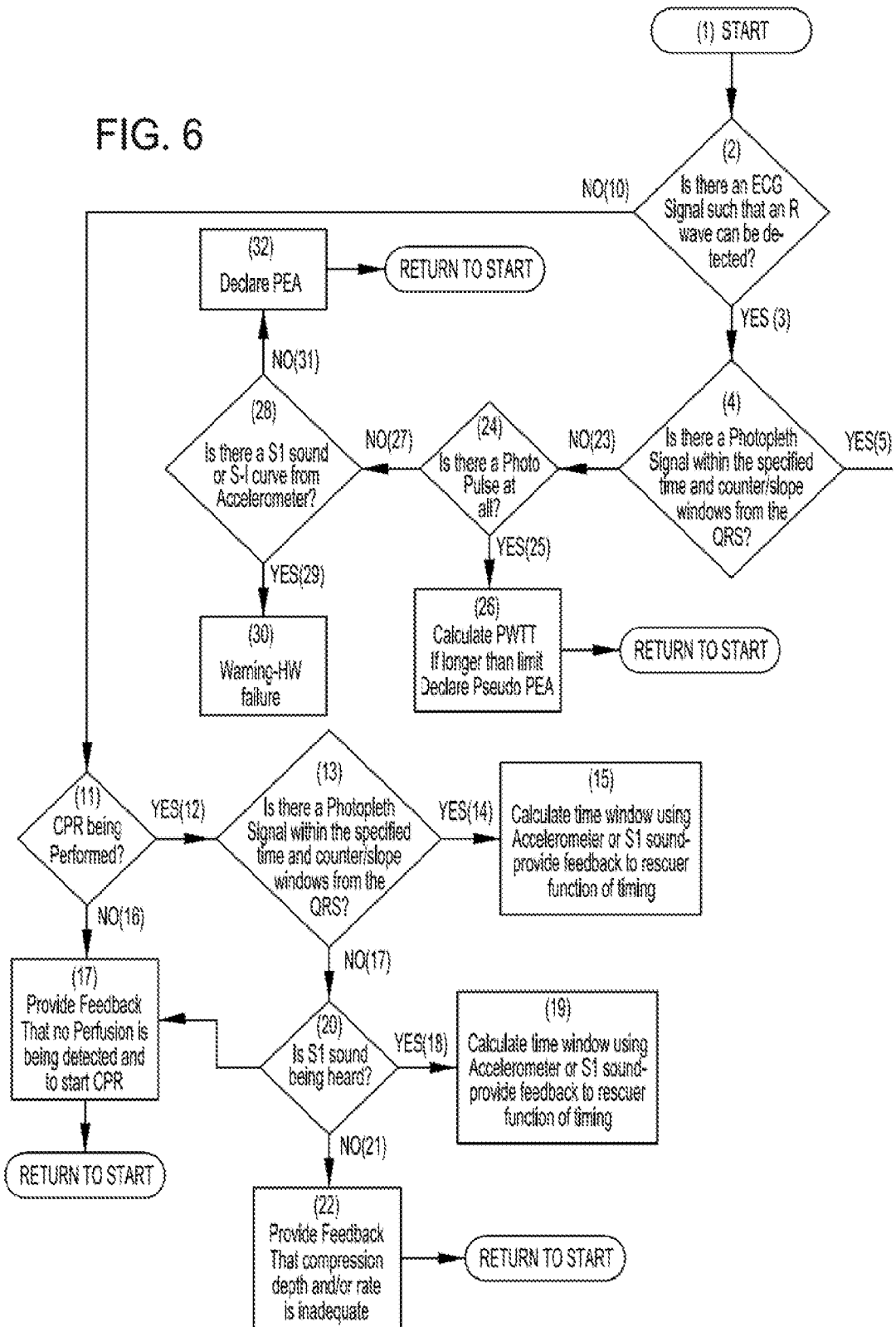
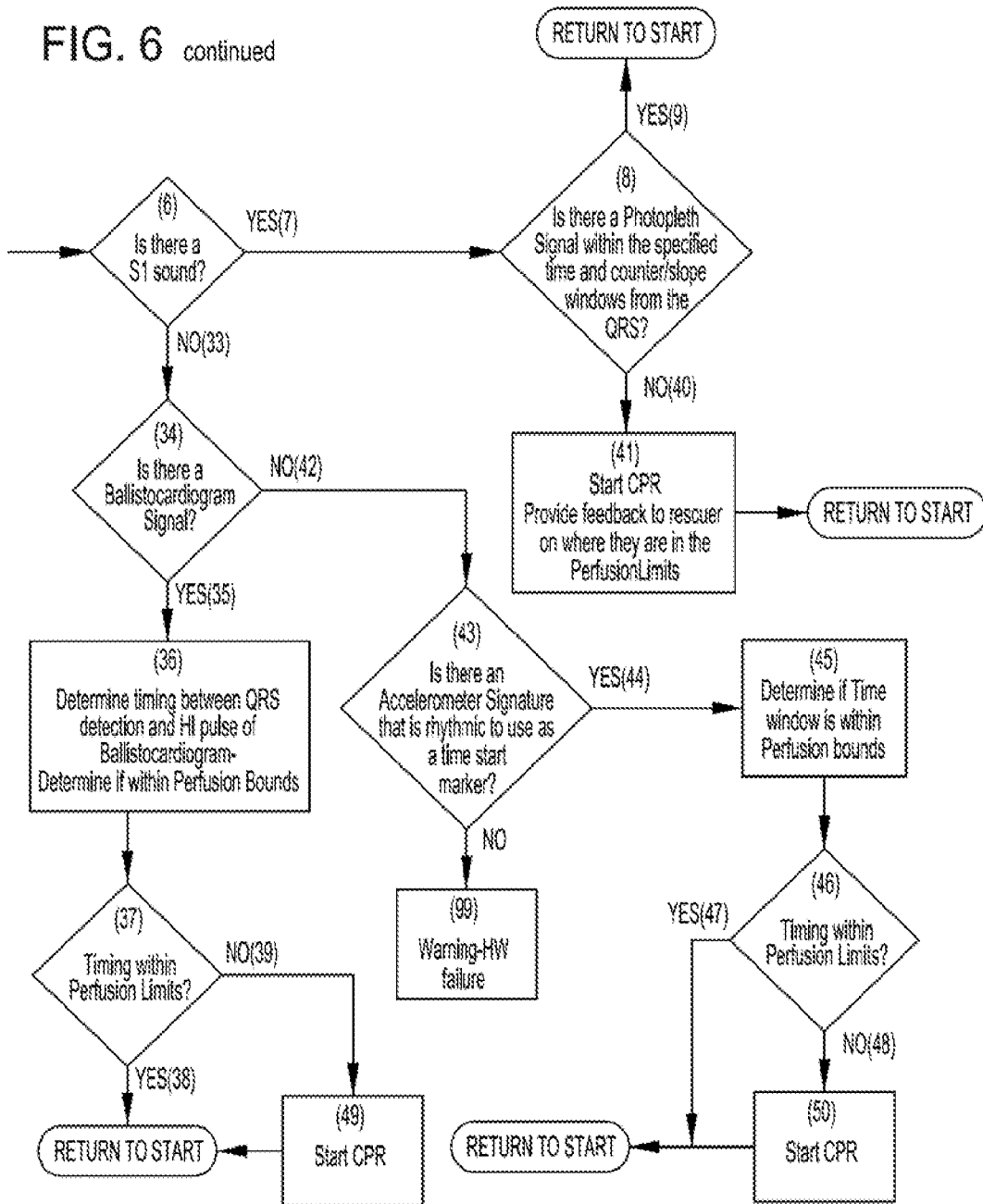


FIG. 6 continued



A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/02(2006.01)i, A61B 5/0402(2006.01)i

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)

A61B 5/02; A61B 5/021; A61B 5/145; A61N 1/36; A61B 5/022; A61B 5/1455; A61B 5/0205; A61B 5/00; A61B 5/0402

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) & Keywords: perfusion index, sensor, cardiac

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category* ^k	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2012-0059267 AI (LAMEGO MARCELO et al.) 08 March 2012 See abstract, paragraphs [0034] -[0037], claim 1 and figure 1.	1-9
Y	US 2006-0009687 AI (DE FELICE CLAUDIO et al.) 12 January 2006 See abstract, paragraphs [0012] -[0015], claims 1-17 and figures 1-2.	1-9
A	US 2011-0172545 AI (GRUDIC GREGORY ZLATKO et al.) 14 July 2011 See abstract, paragraphs [0041] -[0047] and figures 1-2.	1-9
A	US 2008-0091093 AI (AL-ALI AMMAR) 17 April 2008 See abstract, paragraphs [0005] -[0009], [0031] - [0036] and figures 1-3B.	1-9
A	US 2009-0069863 AI (PLESS BENJAMIN D. et al.) 12 March 2009 See abstract, paragraphs [0103] -[0110], claims 1-10 and figure 8.	1-9

 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 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

27 September 2013 (27.09.2013)

Date of mailing of the international search report

27 September 2013 (27.09.2013)

Name and mailing address of the ISA/KR


 Korean Intellectual Property Office
 189 Cheongsu-ro, Seo-gu, Daejeon Metropolitan City,
 302-70 1, Republic of Korea

Facsimile No. +82-42-472-7140

Authorized officer

KIM Tae Hoon

Telephone No. +82-42-481-8407



INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2013/049667

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
us 2012-0059267 AI	08/03/2012	Wo 2012-027613 AI	01/03/2012
us 2006-0009687 AI	12/01/2006	us 7292883 B2 Wo 2005-096922 AI	06/11/2007 20/10/2005
us 2011-0172545 AI	14/07/2011	AU 2009-310388 AI AU 2009-310389 AI AU 2009-310391 AI AU 2009-310392 AI AU 2009-310393 AI AU 2009-310394 AI AU 2009-314391 AI CA 2684155 AI CA 2734474 AI CA 2740646 AI CA 2740646 C CA 2741271 AI CA 2741271 C CA 2741737 AI CA 2741741 AI CA 2741742 AI CA 2741745 AI CA 2775675 AI CN 102186510 A CN 102186511 A CN 102196827 A CN 102196828 A CN 102196829 A CN 102196830 A CN 102203028 A CN 102227635 A EP 2340061 AI EP 2340061 BI EP 2340062 AI EP 2340062 BI EP 2340064 AI EP 2340065 AI EP 2340066 AI EP 2340066 BI EP 2341955 AI EP 2341955 BI EP 2349945 AI EP 2350642 AI EP 2356579 AI EP 2536328 AI EP 2542148 AI EP 2594299 A2 EP 2601984 A2 EP 2601984 A3	06/05/2010 06/05/2010 06/05/2010 06/05/2010 06/05/2010 06/05/2010 20/05/2010 29/04/2010 20/05/2010 06/05/2010 16/07/2013 06/05/2010 19/03/2013 06/05/2010 06/05/2010 06/05/2010 06/05/2010 14/05/2010 14/09/2011 14/09/2011 21/09/2011 21/09/2011 21/09/2011 21/09/2011 28/09/2011 26/10/2011 06/07/2011 26/06/2013 06/07/2011 26/06/2013 06/07/2011 06/07/2011 10/04/2013 13/07/2011 05/12/2012 03/08/2011 03/08/2011 17/08/2011 26/12/2012 09/01/2013 22/05/2013 12/06/2013 07/08/2013

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/049667

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		JP 05016143 B2	05/09/2012
		JP 05118255 B2	16/01/2013
		JP 05138816 B2	06/02/2013
		JP 2012-507347 A	29/03/2012
		JP 2012-507348 A	29/03/2012
		JP 2012-507350 A	29/03/2012
		JP 2012-507351 A	29/03/2012
		JP 2012-507352 A	29/03/2012
		JP 2012-507353 A	29/03/2012
		KR 10-2011-0083691 A	20/07/2011
		KR 10-2011-0083692 A	20/07/2011
		KR 10-2011-0083693 A	20/07/2011
		KR 10-2011-0083694 A	20/07/2011
		KR 10-2011-0086125 A	27/07/2011
		KR 10-2011-0087270 A	02/08/2011
		US 2010-0101981 A1	29/04/2010
		us 2010-0104744 A1	29/04/2010
		us 2010-0106106 A1	29/04/2010
		us 2010-0106115 A1	29/04/2010
		us 2010-0106184 A1	29/04/2010
		us 2010-0106186 A1	29/04/2010
		us 2010-0106187 A1	29/04/2010
		us 2010-0106188 A1	29/04/2010
		us 2010-0126910 A1	27/05/2010
		us 8114126 B2	14/02/2012
		us 8142419 B2	27/03/2012
		us 8192409 B2	05/06/2012
		us 8197467 B2	12/06/2012
		us 8343337 B2	01/01/2013
		us 8388832 B2	05/03/2013
		Wo 2010-051067 A1	06/05/2010
		Wo 2010-051068 A1	06/05/2010
		wo 2010-051070 A1	06/05/2010
		wo 2010-051071 A1	06/05/2010
		wo 2010-051072 A1	06/05/2010
		wo 2010-051073 A1	06/05/2010
		wo 2010-053743 A1	14/05/2010
		wo 2010-053771 A1	14/05/2010
		wo 2010-056539 A1	20/05/2010
		wo 2011-103102 A1	25/08/2011
		wo 2011-109734 A1	09/09/2011
us 2008-0091093 A1	17/04/2008	EP 2073692 A2	01/07/2009
		JP 2010-506614 A	04/03/2010
		us 2013-079610 A1	28/03/2013
		us 8280473 B2	02/10/2012
		wo 2008-045538 A2	17/04/2008
		wo 2008-045538 A3	05/02/2009
us 2009-0069863 A1	12/03/2009	us 2006-0129204 A1	15/06/2006

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/049667

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		US 2006-0265022 AI	23/11/2006
		US 2008-0046026 AI	21/02/2008
		US 2010-0137937 AI	03/06/2010
		US 7341562 B2	11/03/2008
		US 7819812 B2	26/10/2010
		US 7892182 B2	22/02/2011
		US 8353837 B2	15/01/2013
		US 8478419 B2	02/07/2013

专利名称(译)	灌注检测系统		
公开(公告)号	EP2869757A1	公开(公告)日	2015-05-13
申请号	EP2013816551	申请日	2013-07-09
[标]申请(专利权)人(译)	CRONE WILLIAMê		
申请(专利权)人(译)	CRONE , WILLIAM E.		
当前申请(专利权)人(译)	CRONE , WILLIAM E.		
[标]发明人	CRONE WILLIAM E		
发明人	CRONE, WILLIAM E.		
IPC分类号	A61B5/02 A61B5/0402 A61B5/00 A61B5/024 A61B5/026 A61B5/046 A61B5/11 A61B7/00		
CPC分类号	A61B5/02028 A61B5/02416 A61B5/0261 A61B5/0402 A61B5/046 A61B5/11 A61B5/1102 A61B5/746 A61B7/00 A61B2562/0204 A61B2562/0219		
代理机构(译)	maccalli , 马珂		
优先权	61/733871 2012-12-05 US 61/669474 2012-07-09 US 61/733865 2012-12-05 US		
其他公开文献	EP2869757A4		
外部链接	Espacenet		

摘要(译)

根据一些实施例，一种用于检测心脏脉冲的灌注指数的系统包括：第一传感器，其感测人类患者核心的第一生理或环境参数；第二传感器，其感测人类患者核心的第二生理或环境参数。响应于第一和第二感测参数的处理器确定范围从0到10的灌注指数，其反映对人类患者躯干的核心的不充分，边际或足够的血液灌注，以及提供可辨别指示的指示器。灌注指数。还公开了一种响应于感测人类患者核心的第一和第二生理或环境参数来检测心脏脉冲的灌注指数的方法。