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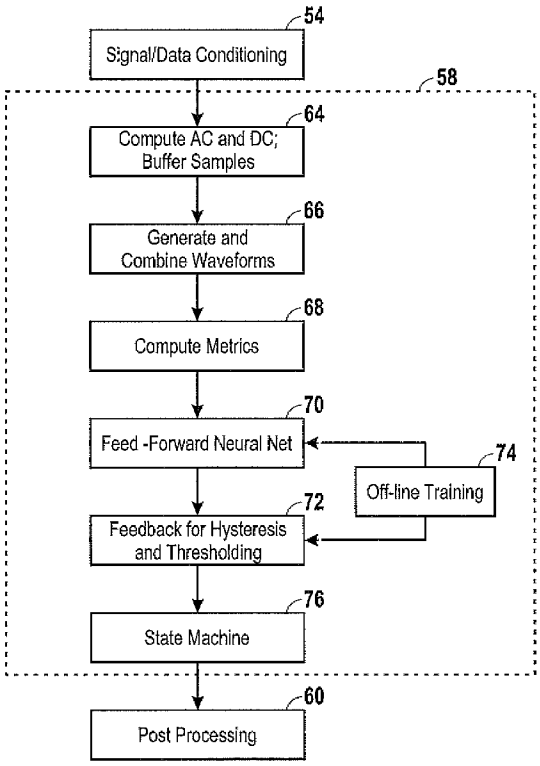

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(57) Abstract: In accordance various embodiments, there is provided a system and method for assessing contact of a sensor with tissue. In various embodiments, there is provided a method for determining whether a sensor is coupled to arterialized tissue comprising generating a combined waveform based on a waveform of a first wavelength and a waveform of a second wavelength. The combined waveform is used to generate a plurality of metrics which are input into a neural network. The neural network generates a probability value indicative of a whether the sensor is coupled to arterialized tissue and, based on the probability value, it is determined whether the sensor is coupled to arterialized tissue.

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METHOD AND APPARATUS FOR ASSESSING CONTACT OF A SENSOR WITH ARTERIALIZED TISSUE

BACKGROUND

[0001] The present invention relates generally to medical devices and, more particularly, to the processing of data in non-invasive medical devices,

[0002] This section is intended to introduce the reader to various aspects of art that may be related to various aspects of the present invention, which are described and/or claimed below. This discussion is believed to be helpful in providing the reader with background information to facilitate a better understanding of the various aspects of the present invention. Accordingly, it should be understood that these statements are to be read in this light, and not as admissions of prior art.

[0003] In the field of medicine, doctors often desire to monitor certain physiological characteristics of their patients. Non-invasive techniques are particularly desirable because they typically provide quick and accurate measurements. One non-invasive technique for monitoring the physiological characteristics of a patient is commonly referred to as pulse oximetry and the devices built based upon pulse oximetry techniques are commonly referred to as pulse oximeters. Pulse oximetry may be used to measure various blood flow characteristics, such as the blood-oxygen saturation of hemoglobin in arterial blood, the volume of individual blood pulsation supplying the tissue, and/or the rate of blood pulsations corresponding to each heart beat of a patient. Such physiological characteristics of a

patient allow doctors and other health cafe personnel to provide the best possible health care for their patients.

[0004] Pulse oximeters typically utilize a non-invasive sensor that has emitters configured to transmit electromagnetic radiation, such as light, through a patient's tissue. The transmitted light is typically selected to be of one or more wavelengths that may be absorbed and scattered by the blood in an amount correlative to the amount of blood constituent in the tissue. The sensor has a detector to photo-electrically detect the absorption and scattering of the transmitted light. One or more of the above physiological characteristics may then be calculated based upon the detected light.

[0005] The accuracy of the calculated physiological parameters depends, in part, on whether the sensor is properly coupled to the skin. If the emitters and detector of the sensor are not in contact with the skin, the light detected by the detector may not represent light that has passed through tissue. As such, any calculations based on the detected light inay not accurately represent physiological parameters.

SUMMARY

[0006] Certain aspects commensurate in scope with the disclosure are set forth below. It should be understood that these aspects are presented merely to provide the reader with a brief summary of certain forms embodiments might take and that these aspects are not intended to limit the scope of the disclosure. Indeed, the disclosure may encompass a variety of aspects that may not be set forth below.

[0007] In accordance with various embodiments, there is provided a method for determining whether a sensor is coupled to arterialized tissue. The method includes providing three signals from three unique wavelengths and generating three waveforms based on the signals from the three unique wavelengths. A waveform of a first wavelength and a waveform of a second wavelength are combined to generate a combined waveform and a plurality of metrics are generated based on the combined waveform. The metrics are input into a neural network which generates a probability value indicative of a whether the sensor is coupled to arterialized tissue. Based on the probability value, it is determined whether the sensor is coupled to arterialized tissue based on the probability value.

[0008] In accordance with various embodiments, there is provided a tangible machine readable medium comprising code for generating a plurality of waveforms based on data obtained by a non-invasive sensor operating a plurality of light sources having unique wavelengths. The tangible machine readable medium also includes code for combining the generated waveforms to form a combined waveform and code for generating metrics based on the combined waveform. Additionally, code for providing the generated metrics to a neural network, wherein the neural network is configured to compute a probability of whether the non-invasive sensor is coupled to tissue is included in the tangible machine readable medium.

[0009] In accordance with various embodiments, there is provided a non¬ invasive medical device comprising a sensor having a plurality of LEDs configured to transmit electromagnetic radiation into arterialized tissue and a photodetector configured to detect the electromagnetic radiation after it has passed through the arterialized tissue

and generate electrical signals representative of the detected electromagnetic radiation. The non-invasive medical device also includes a monitor coupled to the sensor configured to compute waveforms based on the electrical signals generated fay each of the plurality of LEDs and combine the computed waveforms to generate at least two combined waveforms. Additionally, the monitor computes metrics based on the combined waveforms and determines a probability that the sensor is in contact with the arterialized tissue.

[0010] In accordance with various embodiments, there is provided a monitor comprising a processor. The processor is configured to compute waveforms based on electrical signals received from a sensor to which the monitor is coupled, combine the computed waveforms to generate at least two combined waveforms, compute metrics based on the combined waveforms and determine a probability that the sensor is in contact with arterialized tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Certain embodiments are described in the following detailed description and in reference to the drawings in which:

[0012] Fig. 1 illustrates a block diagram of a pulse oximeter system in accordance with an embodiment;

[0013] Fig. 2, is a perspective view of a pulse oximeter system in accordance with an embodiment;

[0014] Fig. 3 is a flow chart illustrating the operation of a pulse oximeter system in accordance with an embodiment; and

[0015] Fig, 4 is a flow chart illustrating the determination of the state of a pulse oximeter system in accordance with an embodiment.

DETAILED _DESCRIPTION

[0016] One or more specific embodiments will be described below. In an effort to provide a concise description of these embodiments, not all features of an actual implementation are described in the specification. It should be appreciated that in the development of any such actual implementation, as in any engineering or design project, numerous implementation specific decisions must be made to achieve developer's specific goals, such as compliance with system related and business related constraints, which may vary from one implementation to another. Moreover, it should be appreciated that such a development effort might be complex and time consuming, but would nevertheless be a routine undertaking of design, fabrication, and manufacture to those of ordinary skill having the benefit of this disclosure.

[0017] In accordance with certain aspects of the present disclosure, a system and method are provided to determine whether a spectrophotometric sensor is appropriately coupled to arterialized tissue. The disclosed techniques may include combining plethysmographic waveforms from three wavelengths and using the combined waveforms to generate metrics that serve as inputs for a neural network. Additionally, a ratio of DC photocurrents (near 890 nm and 1300 nm, for example)

may be input to the neural network which is configured to determine a probability of whether the sensor is in contact with arterialized tissue. If it is determined that the sensor is not appropriately coupled to the arterialized tissue, a notification may be provided to a clinician or caregiver, so that the sensor may be re-positioned to appropriately couple with the tissue.

[0018] Several techniques have previously been implemented to determine whether a sensor is coupled to arterialized tissue. One technique is described in the commonly assigned U.S. Patent No. 6,035,223 ('223 patent) entitled METHOD AND APPARATUS FOR DETERMINING THE STATE OF AN OXIMETRY SENSOR, which is incorporated herein by reference in its entirety for all purposes. The '223 patent teaches the use of a single-hidden layer feed-forward neural network, with additional feedback for hysteresis, that is trained with an appropriate database of patient/sensor data, with input metrics computed from two wavelength signals. The '223 patent may only use two wavelengths that are typically used in pulse oximetiy systems to develop the metrics for the neural net.

[0019] Various embodiments of the present disclosure may include a three wavelength system to compute metrics for the input to a neural network. In various embodiments, metrics are developed based on combinations of waveforms from signals of the three wavelengths, as will be described in detail below. Because the neural network of the'223 patent is similar in operation with the neural network of the present disclosure, reference may be made to the '223 patent for additional information on the operation of the neural network.

[0020] Techniques have also been developed using three wavelengths for determining whether a sensor is in contact with tissue. Specifically, three wavelength techniques commonly assigned U.S. Patent No. 7,277,741 (hereinafter referred to as "the '741 patent) entitled PULSE OXIMETERYMOTION ARTIFACTREJECTION USING NEAR INFRARED ABSORPTION B Y WATER, and U.S. Patent Application 11/521,960 (hereinafter referred to as "the '960 application") entitled PULSE OXIMETRY SIGNAL CORRECTION USING NEAR INFRARED ABSORPTION BY WATER, the teachings of which are also incorporated herein by reference in their entirety for all purposes. These applications do not disclose utilizing a neural network. Rather, they simply disclose a motion-tolerant oximetry system and signal-processing algorithm using signals from three distinct wavelengths. However, the wavelengths described in these references, generally speaking, may be utilized in the presently disclosed system.

[0021] The use of three wavelengths may include providing three LEDs in a sensor, where two of the three LEDs provide signals at wavelengths that are used for pulse oximetry purposes, such as, for example, wavelengths in the red and infrared regions of the electromagnetic spectrum. The third LED, however, may provide a signal having a wavelength that is selected to be mostly absorbed by tissue components, such as water, and absorbed to a lesser extent by hemoglobin. In this context, a fraction of the AC portion of the waveform acquired from the third wavelength may be combined with the AC portions of the waveforms acquired from each of the traditional two pulse oximetry wavelengths, thereby producing two combined waveforms, each containing less correlated artifact not arising from arterial blood than is present in the waveforms acquired from the traditional two oximetiy

wavelengths. This is because the combination of the traditional pulse oximetry wavelengths with a wavelength in a spectral region where water is the dominant absorber allows for motion-related signals to be selectively removed. The combining operations may take into account relative differences of the AC and DC portions of the signals from the various wavelengths, and the same pre-processing (such as band pass or derivative filtering) may be applied to all waveforms prior to the combining of the three wavelength signals. In accordance with the present disclosure, the combined waveforms may be utilized to develop metrics that may be used in a neural net, as will be discussed in greater detail below. As such, reference may be made to the '475 and '960 applications for additional details regarding the theoretical underpinnings as well as technical aspects of combining waveforms.

[0022] Additionally, the co-pending and commonly assigned U.S. Patent Application 11/716,777 entitled METHOD FOR DETECTION OF ABERRANT TISSUE SPECTRA (H-NE-00047/TYHC:0260) is incorporated herein by reference in its entirety for all purposes. This application discloses using a highly absorbed wavelength, in addition to the conventional two wavelengths that are used in pulse oximetry systems, to determine whether a sensor is in contact with tissue. In various embodiments, detected radiation from the highly absorbed wavelength is compared against a threshold to determine whether the sensor is in contact with tissue. In accordance with the present disclosure, the comparison of the highly absorbed wavelength with the threshold may be included as a metric for the neural net.

[0023] Turning to the figures and referring initially to Fig. 1, a block diagram of a sensor and monitoring system 10 is illustrated in accordance with an embodiment. The system 10 is an embodiment and an actual implementation may include more or fewer components as desired for a specific application for which the system 10 is to be used. The system 10 may include a sensor 12 which includes an emitter 14 configured to transmit electromagnetic radiation, such as light, into the tissue of the patient 16. In accordance with one embodiment, the emitter 14 may include three LEDs configured to operate at three different wavelengths, typically in the red and infrared regions of the electromagnetic spectrum. In various embodiments, the emitter 14 may include two LEDs configured to operate at wavelengths suitable for pulse oximetry measurements, while a third LED operates at a third wavelength that is not primarily absorbed by hemoglobin. For example, the third wavelength may be selected based on primarily being absorbed by tissue constituents, such as water, protein, and/or fat, rather than by hemoglobin.

[0024] In accordance with an embodiment, a first LED may operate in the red region of the electromagnetic spectrum, i.e., approximately 600 nm to 750 nm, while the other two LEDs may operate in the near infrared region of the electromagnetic spectrum, i.e., approximately 750 nm to 2500 nm. In particular, for example, a first LED may operate at approximate 660 nm, a second LED may operate at approximately 890 nm and a third LED may operate in the range from about 1150 to 1350 nanometers, such as approximately 1300 nm which is known to be absorbed by water, for example. It should, however, be understood that other regions of the

electromagnetic spectrum may be iised including radio waves, microwaves, visible, ultraviolet, or even X-ray electromagnetic radiation, for example.

[0025] Although the discussion included herein discusses using LEDs, it should be understood that alternative embodiments may employ alternative light sources or a combination of different light sources. For example in an embodiment, a broad spectrum emitter may be used. In yet another embodiment, a scanning light source may be used which may incrementally emit across a broad spectrum of wavelengths.

[0026] The electromagnetic radiation from the emitter 14 may be scattered and/or absorbed by the various constituents of the patient's blood and/or tissues. In an embodiment, a photoelectric detector 18 in the sensor 12 may be configured to detect the scattered and/or reflected light and to generate a signal corresponding to the detected light. The detector 18 may include one or more photodetectors configured to detect light in the electromagnetic regions in which the emitter 14 operates. As such, the type and number of detectors 18 may depend on the particular wavelengths emitted by the emitter 14. For example, in one embodiment, a silicon photodetector may be provided as well as an indium-galiium-arsenide photodetector, so that electromagnetic radiation in the red and infrared regions of the electromagnetic spectrum may be detected.

[0027] The signal generated by the detector 18 may be provided to a monitor 20, such as a pulse oximetry or multi-parameter monitor, such as those available from Nellcor Puritan Bennett L.L.C. and/or Covidien. As illustrated, the monitor 20 includes a microprocessor 22 which may be configured to calculate various physiological parameters, characteristics, and/or other metrics of the patient 16 using algorithms programmed into the monitor 20. The microprocessor 22 may be connected to other component parts of the monitor 20, such as a ROM 26, a RAM 28, and control inputs 30. The ROM 26 may be configured to store the algorithms used to compute the physiological parameters, characteristics, and/or metrics, and the RAM 28 may be configured to store the signals generated by the sensor 12 for use in the algorithms.

[0028] One or more control inputs 30 may be provided to allow a user to interface with the monitor 20. The control inputs 30 may include soft keys, dedicated function keys, a keyboard, and/or keypad type interfaces for providing parameters, data, and/or instructions to the monitor 20. h1 certain embodiments, the control inputs 30 may also include speech or tone recognition or other audio, remote, and/or hands-free command input type devices.

[0029] As mentioned above, signals may be passed from the sensor 12 to the monitor 20 for processing. In one embodiment, the signals may be amplified and filtered by an amplifier 32 and a filter 34, respectively, before being converted to digital signals by an analog-to-digital converter 36. The signals may then be stored in

RAM 28 and/or used to determine the physiological parameters, characteristics, and/or metrics.

[0030] A light drive unit 38 in the specti'ophotometïc monitor 20 may control the timing of the emitters 14. While the emitters 14 may be manufactured to operate at one or more wavelengths, variances in the wavelengths actually emitted may occur which may result in inaccurate readings. To help avoid inaccurate readings, an encoder 40 and decoder 42 may be used to calibrate the monitor 20 to the actual wavelengths emitted by the emitters 14. The encoder 40 may be a resistor, for example, whose value corresponds to one or more of the emitter wavelengths so that proper coefficients stored in the monitor 20 may be selected. In an embodiment, the encoder 40 may be a memory device, such as an EPROM, that stores information, such as information related to the emitter wavelengths or the coefficients themselves, for example. Once the coefficients are determined by the monitor 20, they may be inserted into the algorithms in order to calibrate the calculations that are being performed by the system 10.

[0031] The monitor 20 may be configured to display the calculated physiological parameters, such as blood oxygen saturation and/or pulse rate for example, on display 44. The display 44 may show the calculated values numerically and/or as a waveform over time. Additionally, any notifications or alerts prompted by abnormal measurements, calculated values and/or by poor contact between the sensor and the patient's tissue, as discussed below, may be displayed.

[0032] An illustration of an embodiment of the sensor 12 and monitor 20 are illustrated in Fig. 2. As illustrated, the sensor 12 maybe a reflectance-type sensor that is configured to couple to the forehead of a patient. In an alternative embodiment (not shown), the sensor 12 may be configured as a transmission-type sensor. A sensor cable 46 may connect the sensor 12 to the monitor 20. As will be appreciated by those skilled in the art, the sensor 12 and/or the sensor cable 46 may include or incorporate one or more integrated circuit devices or electrical devices, such as a memory, processor chip, or resistor, to facilitate or enhance communication between the sensor 12 and the patient monitor 20. For example, the cable 46 may include the encoder 40 discussed above for indicating information which may be used by the monitor 20 in operation. Additionally, the sensor cable 46 may be an adaptor cable, with or without an integrated circuit or electrical device, for facilitating communication between the sensor 12 and various types of monitors, including alternative versions of the monitor 20 or monitors made by different manufacturers. Furthermore, the cable 46 may be permanently coupled to the sensor 12 to prevent removal of the sensor 12 or, alternatively, the cable 46 may be removably coupled to the sensor 12 for situations where it may be desirable to have a disposable sensor 12,

[0033] To supplement the monitoring functions provided by the monitor 20, the monitor 20 may be coupled to a computing system 48 via a cable 50 connected to an input port and/or via a cable 52 connected to a communications port. The computing system 48 may be configured to provide additional computational power as well as additional storage resources for calculated physiological data. Additionally, the computing system 48 may be networked with other computer systems within a healthcare facility.

[0034] The sensor 12 may be placed on the patient 16 in a location conducive to measurement of the desired physiological parameters. Common pulse oximetty sensor sites include a patient's fingertips, toes, forehead, or earlobes. As stated above, the reliability of the spectrophotometry measurement is related to the accurate detection of transmitted or reflected light that has passed through the patient's tissue. To achieve accurate detection of the transmitted or reflected light, the sensor 12 should remain in contact with the patient's tissue. Failure to do so can result in inaccurate measurement of the desired physiological parameters. An inaccurate measurement may also be the result of attenuation or scattering of signal transmitted through air or substances other than arterialized tissue.

[0035] In accordance with an embodiment, combined plethysmographic waveforms from the three signals of different wavelengths are used to determine whether the sensor 12 is in contact with arterialized tissue. In various embodiments, for example, the waveforms from conventional red and IR wavelengths used for pulse oximetry (approximately 660 and 890 nm, for example) may be combined with the waveform of a third wavelength (approximately 1300 nm, for example) to develop metrics used in a neural network which is configured to determine the probability of whether the sensor 12 is in contact with tissue. The neural network may be executed by the processor 22 of Fig. 1, the computer system 48 of Fig. 2 or, alternatively, executed in hardware/firmware of an ASIC (not shown), for example.

[0036] Neural networks may be represented symbolically as an interconnected network of nodes arranged in a specific topology or configuration. Links between

nodes represent dependencies between nodes and have weights associated with each link representing the strengths of the dependencies. Artificial neural networks may include an input layer, hidden or processing layers, and an output layer. The links between nodes are adjusted for specific tasks by training of the network, which involves exposing the network to representative data sets to be processed. Output from the network may be compared to desired results and corresponding adjustments may be made to reduce any discrepancies between the desired output and the actual output. The metrics described herein include inputs to the neural network and quantify aspects of the behavior of data retrieved over a period of several seconds.

[0037] A feedback layer may provide threshold comparison information for determining the probability of a particular condition of the sensor, i.e., whether it is in contact with arterialized tissue or not. The feedback layer may have built in hysteresis. The coefficients for both the neural network and feedback layer may be determined by off-line training algorithms which are responsible for finding and optimizing the relationships between the inputs and the outputs.

[0038] A state machine may receive a determination as to whether the sensor is in contact with arterialized tissue from the feedback layer and deliver one of a plurality of sensor state indications to the processing subsystems for both pulse rate and oxygen saturation algorithms, thereby recommending appropriate actions for the subsystems. Generally, the sensor state indications may be related to the determination that the sensor is in contact with tissue or not, The possible actions in response to the state indications may include updating the oxygen saturation and pulse

rate outputs, holding the current oxygen saturation and pulse rate outputs, or clearing the current oxygen saturation and pulse-rate outputs. The monitor 20 may be configured to provide appropriate audio and/or visual indications based on the determined sensor state.

[0039] The neural network may be trained according to an algorithm that is responsible for finding and optimizing the relationships between the neural network's inputs (the metrics) and the output. The trained neural network may be implemented as an array of dot products and functions. Retraining may be performed by providing updated coefficients. For example, the neural network may be trained on large database containing data representative of different sensor states. The data may be classified as indicating the sensor state and, therefore, may be used to set the thresholds for a probability determination of sensor states by the neural network based on the input metrics.

[0040] The metrics that serve as inputs to the neural network may include an AC amplitude metric and/or AC amplitude variability input metric described in detail in the '223 patent. The AC amplitude metric and/or variability input metric may be derived from at least one combined waveform, i.e., a waveform from the combination of the first and the third wavelengths, or a waveform from the combination of the second and third wavelengths, for example, hi an embodiment, the AC amplitude metric is the difference between the maximum and minimum digitized IR signal level over an appropriate period. In accordance with a present embodiment, this metric may be determined using a combined waveform of two wavelengths, such as waveforms

from an 890 nm signal and 1300 nm signal, for example. As discussed above, the combination of waveforms is discussed in detail in the '475 and '960 patent applications. As such, reference may be made to those applications regarding the specifics of combining the waveforms.

[0041] The AC amplitude metric may be sensitive to rapid changes in light absorption. Very high or very low values of the AC amplitude metric may be likely indicators that the sensor is not coupled to tissue. Because the light level can change dramatically when the sensor comes off, the max-min difference may be scaled in dB. The metric may then be averaged using a single pole FIR filter with an appropriate time constant. This averaging may make the metric less sensitive to irregular pulse amplitudes that occur during arrhythmias and to zero modulations that could be computed during gain and LED adjustments. Arithmetic averaging may be used when this average is increasing, while geometric averaging may be used when the metric is decreasing. Generally, this metric will be veiy large while the sensor 12 is being applied to arterial ized tissue, and the geometric averaging may help assure a faster convergence time once the application of the sensor to the tissue is completed.

[0042] In an embodiment, the variability metric is a relative variability of the AC amplitude and is computed for the unaveraged AC amplitude that was derived from a combined waveform of two wavelengths. The difference in the unaveraged AC amplitude between consecutive computation periods may be squared, and this squared difference may be averaged with a single-pole IJR filter with an appropriate time constant and the square root is taken. When the average is increasing, arithmetic

averaging may be used, and when it is decreasing, geometric averaging may be used. Similar to the AC amplitude metric, the variability metric may be very large when the sensor falls off or is reapplied to arterialized tissue, and geometric averaging may provide for quicker convergence when the sensor is applied.

[0043] The averaged AC modulation and the average variation may be limited to a maximum value in accordance with one embodiment. In an embodiment, this limits the range of the metric over which the neural network is to be trained and reduces convergence time after the sensor is reapplied to the tissue.

[0044] In addition to the AC modulation metric and the variation metric, a correlation (or similarity) input metric may be derived using two combined waveforms. In an embodiment, the correlation metric may be based on the degree to which the combined waveforms are correlated and may be computed from the combined waveforms that have, for example, been bandpass filtered, normalized and whitened, where the whitening filter is used to downweight lower frequencies because motion artifact will typically occur at frequencies lower than the pulse rate. The formula for the correlation metric is:

$$\sqrt{\frac{\sum_{i=0}^{M-1}(WaveformA_{t-i} - WaveformB_{t-i}R)^2}{\sum_{i=0}^{M-1}WaveformA_{t-i}^2}},$$

where

$$R = \frac{\sum_{i=0}^{M-1} WaveformB_{t-i} WaveformA_{t-i}}{\sum_{i=0}^{M-1} WaveformB_{t-i}^2};$$

T is in samples;

M is set to define an appropriate computation period;

WaveformA is the combined waveform of the red wavelength and the third wavelength; and

WaveformB is the combined waveform of the IR wavelength and the third wavelength.

[0045] As mentioned above, the third wavelength may be selected based on absorption by tissue constituents, such as water, for example, and may be a wavelength within the IR region of the electromagnetic spectrum. For example, the correlation input metric may be derived from the combined waveforms of the 660 and 1300 nm waveforms and the 890 and 1300 nm waveforms. In an embodiment, the correlation metric is zero in case of division by zero, or if R is zero or if the expression under the square root is zero. The correlation metric may range from zero to one. The correlation metric may be averaged with a single-pole ITR filter with an appropriate time constant because large transient noise artifacts may cause a sudden change in its value. The extra averaging may prevent the neural network from spuriously reporting a sensor off condition due to transients.

[0046] A shape-indicating metric and a regularity metric may also be derived using combined waveforms which, as discussed above, reduces the noise effects and may provide for more accurate determination of whether the sensor is in contact with

tissue. A typical human photoplethysmographic pulse (as represented, for example by a waveform) is generally asymmetrical while some non-pulsatile signals are more likely to be symmetrical. The asymmetry of the pulse shape may cause the derivative of the digitized pulse waveform to have a negative skew. This derivative value may be averaged over a small number of samples to reduce high-frequency noise that is not indicative of whether the sensor is in contact with arterialized tissue. The skewness of this averaged derivative may then be computed in accordance with the teachings of the '223 patent, but where the combined waveforms discussed herein are used rather than a waveform based on a single wavelength.

[0047] In accordance with the teachings of the '223 patent, a regularity metric (referred to as "harmonicity" in '223) may be computed as the maximum autocorrelation of the photoplethysmograph over a range of time intervals corresponding to the expected range of human pulse periods (e.g. 0.24 - 3.0 seconds for an expected pulse-rate range of 20-250 BPM). However, the combined waveforms discussed herein may be used rather than a waveform of based on a single wavelength. Alternatively, a regularity metric may be computed as a measure of the variability of a series of several pulse periods, wherein the pulses and periods thereof are determined using the combined waveforms. For example, this pulse-period variability could be computed as the coefficient of variation (standard deviation of pulse periods / mean pulse periods), or as (maximum period - minimum period) / mean period.

[0048] The difference between the DC portion acquired from the third wavelength and the DC portion acquired from one of the traditional two wavelengths

may be incorporated as an additional input to the sensor off neural net. This difference tends to be highly indicative of whether an oximetry sensor is applied to the tissue because, as mentioned above, the third wavelength is selected based on its absorption by water, which makes up about 60% of human tissue, and the other two wavelengths are not significantly absorbed by water. Therefore, the third wavelength may have a much lower DC level when applied to tissue than the other wavelengths.

[0049] If the sensor is not in contact with tissue, any light returning to the photodetector(s) will likely reflect off a surface or be substantially unattenuated because it passes through air, which does not absorb it as strongly as tissue, rather than diffuse through a water-based material. The third wavelength may have a DC level that is significantly larger in proportion to the DC levels of the other wavelengths. The metric derived from the DC differences may take into account differences in emitter brightness or detector sensitivity at the respective wavelengths, as well as any variable gain stages in the oximeter hardware.

[0050] Additionally, the DC difference that is indicative of the sensor being applied to tissue may depend on additional factors, such as the emitter-detector spacing and if the sensor uses a reflectance or transmission geometry. For sensors having a 10 mm spacing, a 1300 nm DC level at least 15dB lower than the 890 nm DC level may be indicative that a reflectance or transmission sensor designed for application to an adult finger is in fact attached to tissue. Furthermore, the sensor and site specific characteristics may be encoded in the oximetry sensor, for instance in a digital memory chip.

[0051] In one embodiment, the combined-waveform derived AC amplitude metric, the AC amplitude variability input metric, the correlation input metric, and the regularity metric, as well as the difference between the DC portion acquired from the third wavelength and the DC portion of one of the other wavelengths may be included as inputs to the neural network. The difference between the DC portions may be used to bias the input to the feed-forward neural network's output node, prior to any feedback, with the bias being determined heuπsticatly. Alternatively, the DC differences may be input to the neural networks hidden layer, using it as a variable basis to the output node to eliminate the need for extensive third wavelength data for retraining the entire neural network. In accordance with the teachings of the '223 patent, the neural net inputs in this embodiment further comprise the shape-indicating (i.e. skewness) metric and metrics of DC variability and slope, all derived from a single wavelength. The metrics of DC variability and slope are Metrics 4 and 5, respectively, of the '223 patent.

[0052] Turning to Fig. 3, a flow chart of a technique 50 for operation of a pulse oximetry system is illustrated, according to an embodiment hi this embodiment, the technique 50 begins by acquiring a signal, as indicated at block 52. In various embodiments, signal acquisition may occur as the detector 18 receives the electromagnetic radiation from emitters 14 and generates a photoelectric current. Subsequently, signal and data conditioning may occur, as indicated at block 54. The data conditioning may include the analog-to-digital conversion, performing a natural logarithm function on the data, filtering the data using an infinite impulse response (HR) filter and and/or normalizing the data. Following the conditioning, oxygen

saturation and pulse rate calculations may be performed and waveforms may be generated, as indicated at block 56. The waveforms may then combined, as discussed herein. A sensor state determination using a neural net may be made based on the combined waveforms, as indicated by block 58.

[0053] According to an embodiment, Fig. 4 illustrates the signal state determination block 58 in greater detail. As illustrated in FIG. 4, the signal state determination of block 58 includes computing metrics to determine whether the sensor is properly coupled to arterialized tissue. In an embodiment, after a signal has been conditioned (block 54) AC and DC elements of the signal are computed and signal samples may be buffered, as indicated at block 64. Waveforms may be generated based on the signals and the generated waveforms may be combined, as indicated at block *66,* Various metrics may be computed using the combined waveforms as discussed in detail above, as indicated at block 68. The metrics may then provided to a feed-forward neural network, as indicated at block 70. The neural network may determine the probability of the state of the sensor according to the metrics which have been computed. The probability may be presented to feedback for hysteresis and thresholding, as indicated at block 72. Offline training of the neural network and feedback may be provided as indicated at block 74.

[0054] A number of neural-net training techniques, such as the Levenberg-Marquardt back-propagation method, are known to those skilled in the art of signal processing. In an embodiment, offline training of the feed-forward neural net 70 may be accomplished using a set of manually classified pulse-oximetry data that covers a

broad range of monitoring conditions with sensors both applied and not applied to arterialized tissue, including periods where the sensor is being applied or removed from tissue. If memory constraints imposed by the offline training algorithm limit the size of the training set, the training set may be a random sampling of the manually classified data. The feedback layer 72 may be implemented in accordance with the teaching of the '223 patent, which implementation is sufficiently simple that its coefficients may be optimized manually, utilizing a training set of temporally continuous data sampled at an interval equal to interval at which the feedback layer is to evaluate the data (e.g. once per second).

[0055] A sensor "on" or sensor "off" signal may then provided to a state machine, as indicated at block 76, that is configured to provide a signal to the post processing mechanism, as indicated at block 60. Accordingly, the signal state determination (block 58) may provide a signal indicative of whether the sensor is in contact with arterialized tissue to a post processing system (block 60). Additionally, the computed oxygen saturation and pulse rate calculations may be provided to post processing mechanism. The post processing mechanism may then determine the output to be displayed as illustrated in Fig. 3 at block 62.

[0056] While the invention may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and have been described in detail herein. However, it should be understood that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling

within the spirit and scope of the invention as defined by the following appended claims.

CLAIMS

What is claimed is:

1. A method for determining whether a sensor is coupled to arterialized tissue comprising:

providing three signals comprising three unique wavelengths;

generating three waveforms based at least in part upon the signals from the three unique wavelengths;

combining a waveform of a first wavelength and a waveform of a second wavelength to generate a combined waveform;

generating a plurality of metrics based on the combined waveform;

inputting the plurality of metrics into a neural network;

generating a probability value indicative of a whether the sensor is coupled to arterialized tissue; and

determining whether the sensor is coupled to arterialized tissue based at least in part upon the probability value.

2. The method of claim 1, further comprising:

combining the waveform of the second wavelength and a waveform of a third wavelength to generate a second combined waveform;

generating a plurality of metrics based on the combined waveform and the second combined waveform;

inputting the plurality of metrics into a neural network;

generating a probability value indicative of a whether the sensor is coupled to arterialized tissue; and

determining whether the sensor is coupled to arterialized tissue based at least in part upon the probability value.

3. The method of claim 1, wherein computing a plurality of metrics comprises computing an AC amplitude metric and a variability metric.

4. The method of claim 2, comprising computing a regularity metric based at least in part upon the combined wavelength and a correlation metric based at least in part upon the combined wavelength and the second combined wavelength.

5. The method of claim 2 comprising computing a metric based at least in part upon a difference between a DC portion of the waveform from the second wavelength and the DC portion acquired from the waveform from either the first wavelength or the third wavelength.

6. The method of claim 5, wherein the metric based at least in part upon the difference between DC portions of wavelengths takes into account differences in emitter brightness and detector sensitivity as the respective wavelengths.

7. The method of claim 5, wherein the metric based at least in part upon the difference between DC portions of wavelengths takes into account variable gain stages in the hardware for the respective wavelengths.

8. The method of claim 2, wherein the first and second wavelengths are generally in an infrared portion of the electromagnetic spectrum and the third wavelength is generally in the red portion of the electromagnetic spectrum.

9. The method of claim 8 wherein the first wavelength is approximately 890 nm the second wavelength is approximately 1300 nm, and the third wavelength is approximately 660 nm.

10. The method of claim 1, wherein the second wavelength is primarily absorbed by water constituents in the tissue.

11. The method of claim 10, wherein the second wavelength is generally in the near-infrared region of the electromagnetic spectrum.

12. The method of claim 1, wherein the third wavelength is generally in the red region of the electromagnetic spectrum.

13. The method of claim 2, wherein the first wavelength is generally in the infrared region of the electromagnetic spectrum.

14. A tangible machine readable medium having instructions stored thereon, which, if executed cause a method to be performed, the method comprising:

generating a plurality of waveforms based at least in part upon data obtained by a non-invasive sensor operating a plurality of light sources having unique wavelengths;

combining the generated waveforms to form a combined waveform;

generating metrics based at least in part upon the combined waveform; and

providing the generated metrics to a neural network, wherein the neural network is configured to compute a probability of whether the non-invasive sensor is coupled to tissue.

15. The tangible machine readable medium of claim 14, wherein the generating a plurality of waveforms comprises generating three waveforms based at least in part upon data obtained three light sources having unique wavelengths.

16. The tangible machine readable medium of claim 15, wherein the combining waveforms comprises combining a first waveform with a second waveform, wherein the first waveform is based at least in part upon data from a first light source operating in an infrared region of the electromagnetic spectrum and the second waveform is generated based at least in part upon data from a second light source having a wavelength primarily absorbed by water.

17. The tangible machine readable medium of claim 16, wherein the combining waveforms comprises combining the second waveform with a third waveform, the third waveform being generated based at least in part upon data from a light source operating in the red region of the electromagnetic spectrum.

18. The tangible machine readable medium of claim 14 comprising determining whether the non-invasive sensor is in contact with the tissue.

19. A non-invasive medical device, comprising:

a sensor comprising:

a plurality of LEDs capable of transmitting electromagnetic radiation into arterialized tissue; and

a photodetector capable of detecting the electromagnetic radiation after it has passed through the arterialized tissue and generating electrical signals based at least in part upon the detected electromagnetic radiation; and

a monitor coupled to the sensor, wherein the monitor is configured to:

compute waveforms based at least in part upon the electrical signals generated by each of the plurality of LEDs;

combine the computed waveforms to generate at least two combined waveforms;

compute metrics based at least in part upon the combined waveforms; and

determine a probability that the sensor is in contact with the arterialized tissue.

20. The non-invasive medical device of claim 19, wherein the plurality of LEDs comprises a first LED operating generally in the infrared region of the electromagnetic spectrum, a second LED operating generally at a wavelength that is primarily absorbed by water and a third LED operating generally at a wavelength in the red region of the electromagnetic spectrum.

21. The non-invasive medical device of claim 20, wherein combining the computed waveforms comprises combining a waveform for the first LED with the waveform for the second LED, and combining the waveform for the second LED with the waveform for the third LED.

22. The non-invasive medical device of claim 20, wherein the first LED operates at approximately 890 nm, the second LED operates at approximately 1300 nm and the third LED operates at approximately 660 nm.

23. A monitor comprising:

a processor configured to:

compute waveforms based at least in part upon electrical signals received from a sensor to which the monitor is coupled;

combine the computed waveforms to generate at least two combined waveforms;

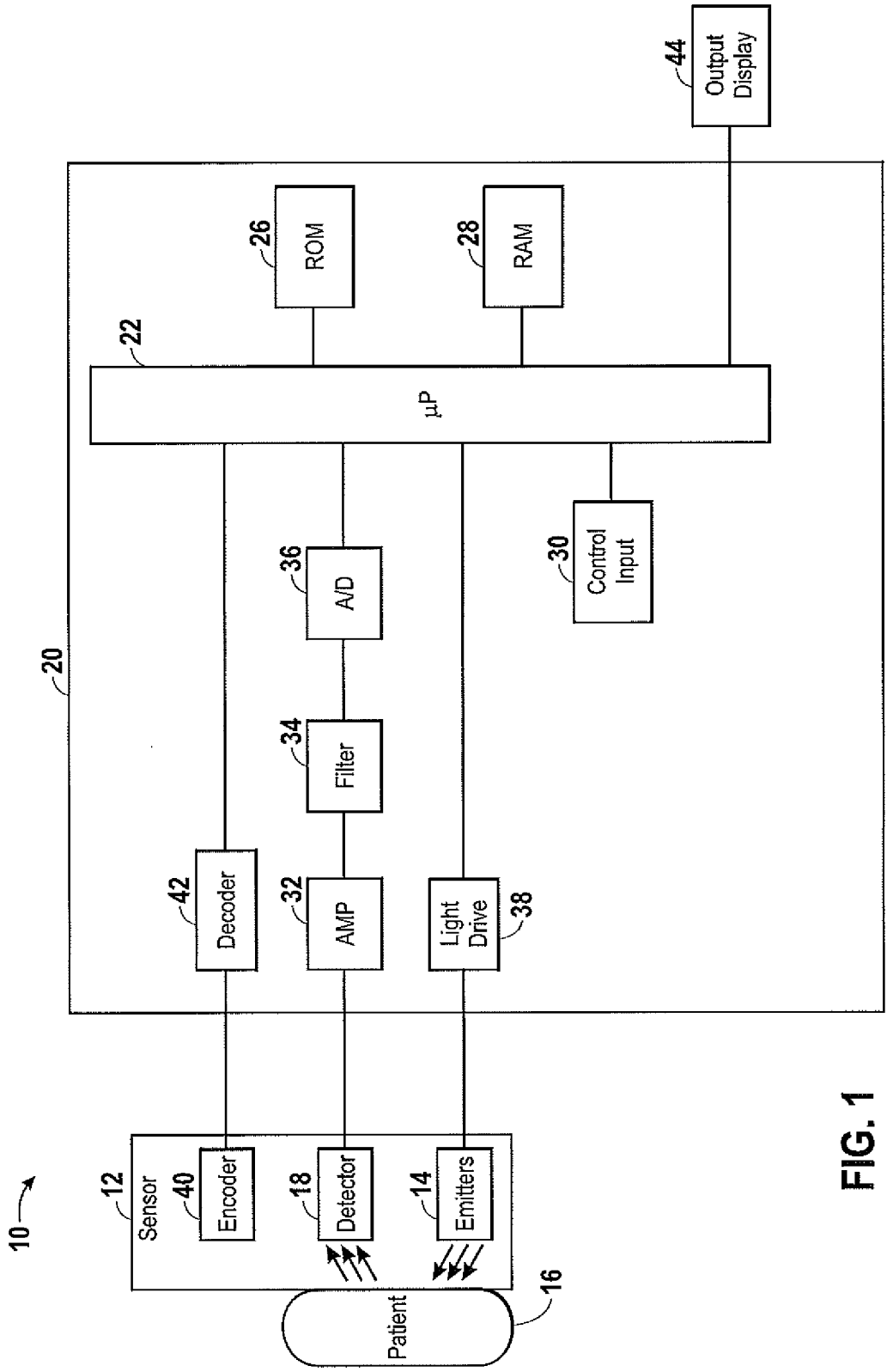
compute metrics based at least in part upon the combined waveforms; and

at least in part upon said metrics, determine a probability that the sensor is in contact with arterialized tissue,

24. The monitor of claim 23 comprising a notification system capable of indicating to a caregiver that the sensor is not in contact with arterialized tissue.

25. The monitor of claim 23, wherein the monitor is configured to compute physiological parameters based at least in part upon the electrical signals received from the sensor.

26. The monitor of claim 25 comprising a display, wherein the monitor is configured to provide computed physiological parameters to the display.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12
Sensor
40
Encoder
18
Detector
14
Emitters
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Patient
20
42
Decoder
32
AMP
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Filter
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A/D
38
Light Drive
22
μP
26
ROM
28
RAM
30
Control Input
44
Output Display

FIG. 1

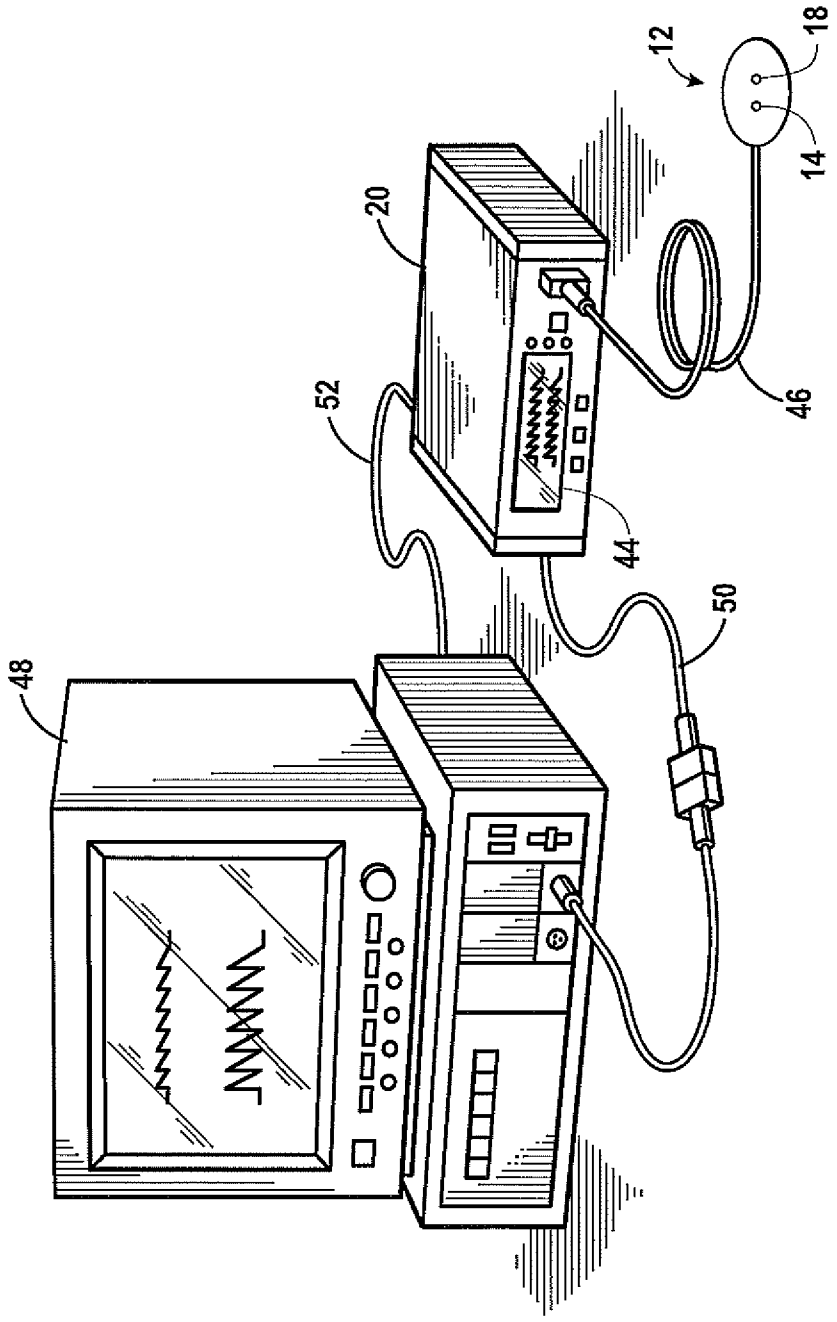

FIG. 2

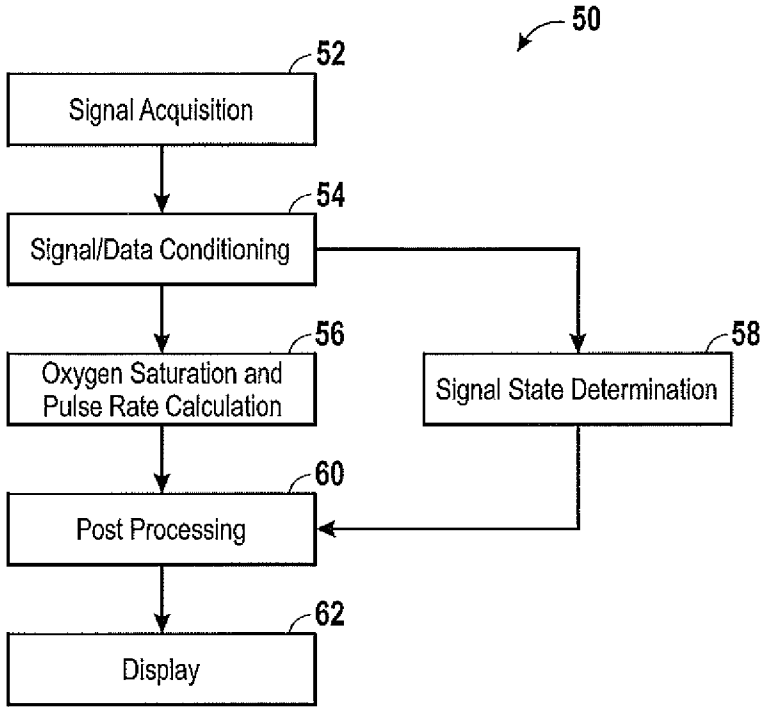
50
52
Signal Acquisition
54
Signal/Data Conditioning
56
Oxygen Saturation and Pulse Rate Calculation
58
Signal State Determination
60
Post Processing
62
Display

FIG. 3

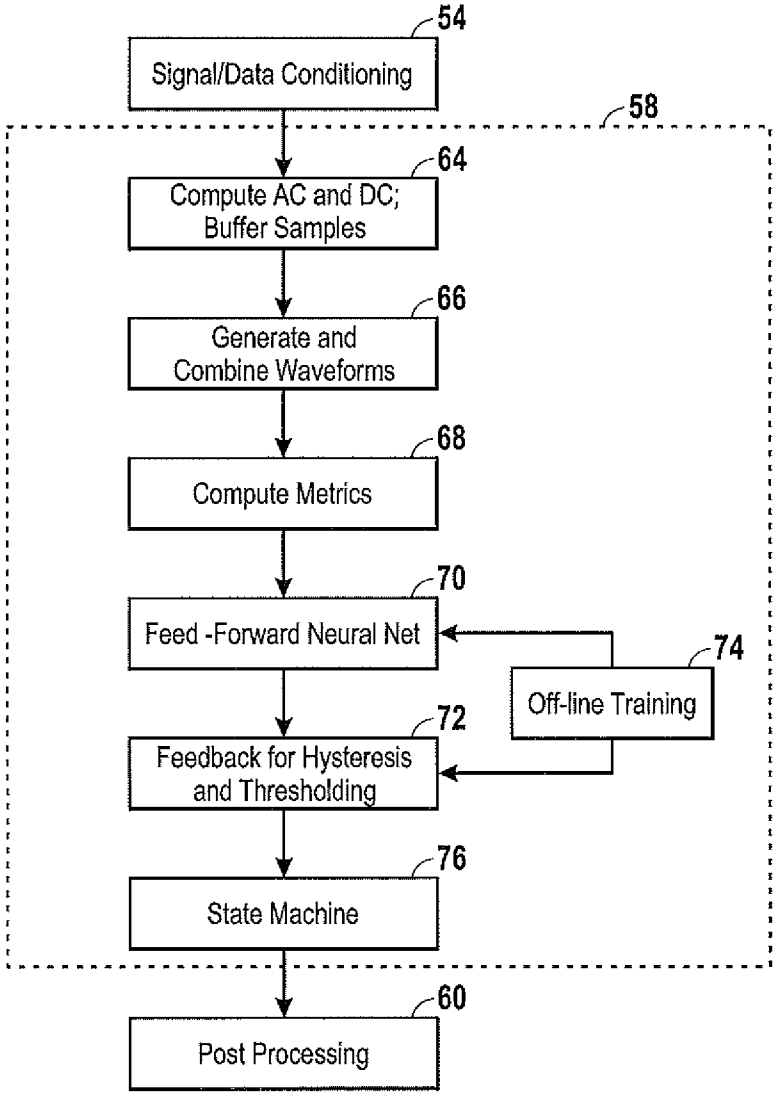
54
Signal/Data Conditioning
58
64
Compute AC and DC; Buffer Samples
66
Generate and Combine Waveforms
68
Compute Metrics
70
Feed -Forward Neural Net
74
Off-line Training
72
Feedback for Hysteresis and Thresholding
76
State Machine
60
Post Processing

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/088307

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00

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

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

Electronic data base consulted during the international search (name of data base and, where practical search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate of the relevant passages	Relevant to claim No
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Y	WO 02/058552 A (DATEX OHMEDA INC [US]) 1 August 2002 (2002-08-01) page 13, line 4 - line 29	1-18
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[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categones of alled documents

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

'E' earlier document but published on or after the international filing dale

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

[1]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 pnority date claimed

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

[1]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

[1]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 docu¬ments, such combination being obvious to a person skilled in the art

[1]S" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 March 2009	06/04/2009

Name and mailing address of the ISA/	Authonzed officer
European Patent Office, P B 5818 Patentlaan 2 NL - 2260 HV Ri|swi|k Tel (+31-70) 340-2040, Fax (+31-70) 340-3016	Bengtsson, Johan

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/088307

C(Conti πuattoπ). DOCUMENTS CONSIDERED TO BE RELEVANT

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Information on patent family members

International application No
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