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(54) **PULSE OXIMETRY RELATIONAL ALARM SYSTEM FOR EARLY RECOGNITION OF INSTABILITY AND CATASTROPHIC OCCURRENCES**

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(57) **ABSTRACT**

A relational pulse oximetry alarm system and method is presented for earlier identification of the occurrence of an adverse clinical event. The system includes a pulse oximeter based microprocessor alarm system which provides an alarm based on a relational conformation of a plurality of time series and further based on the recognition of specific dynamic patterns of interaction between a plurality of corresponding and related time series including the occurrence of pathophysiologic divergence of two or more time series outputs. The processor is programmed to compare a first time series to a second time series to produce a comparison result, to identify a relationship between the first time series and the second time series, to identify a relational threshold breach, and to output an alarm based on the relational threshold breach. The system can include an oximeter testing system for predicting the timeliness of the response of the alarm of a pulse oximeter to the occurrence of an adverse clinical event.

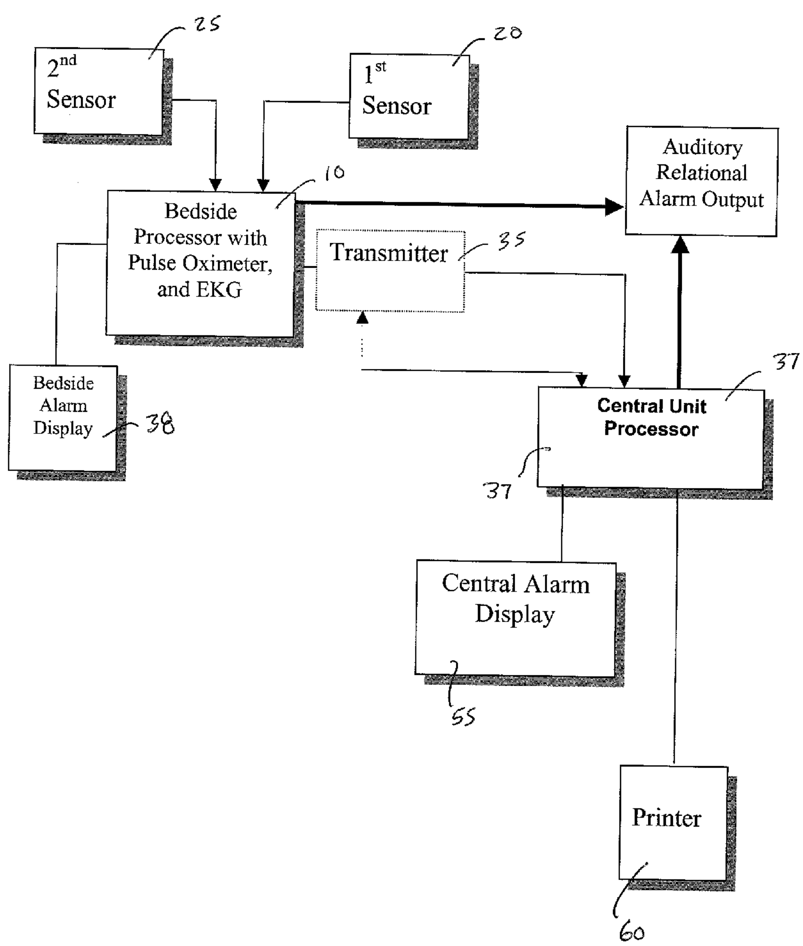
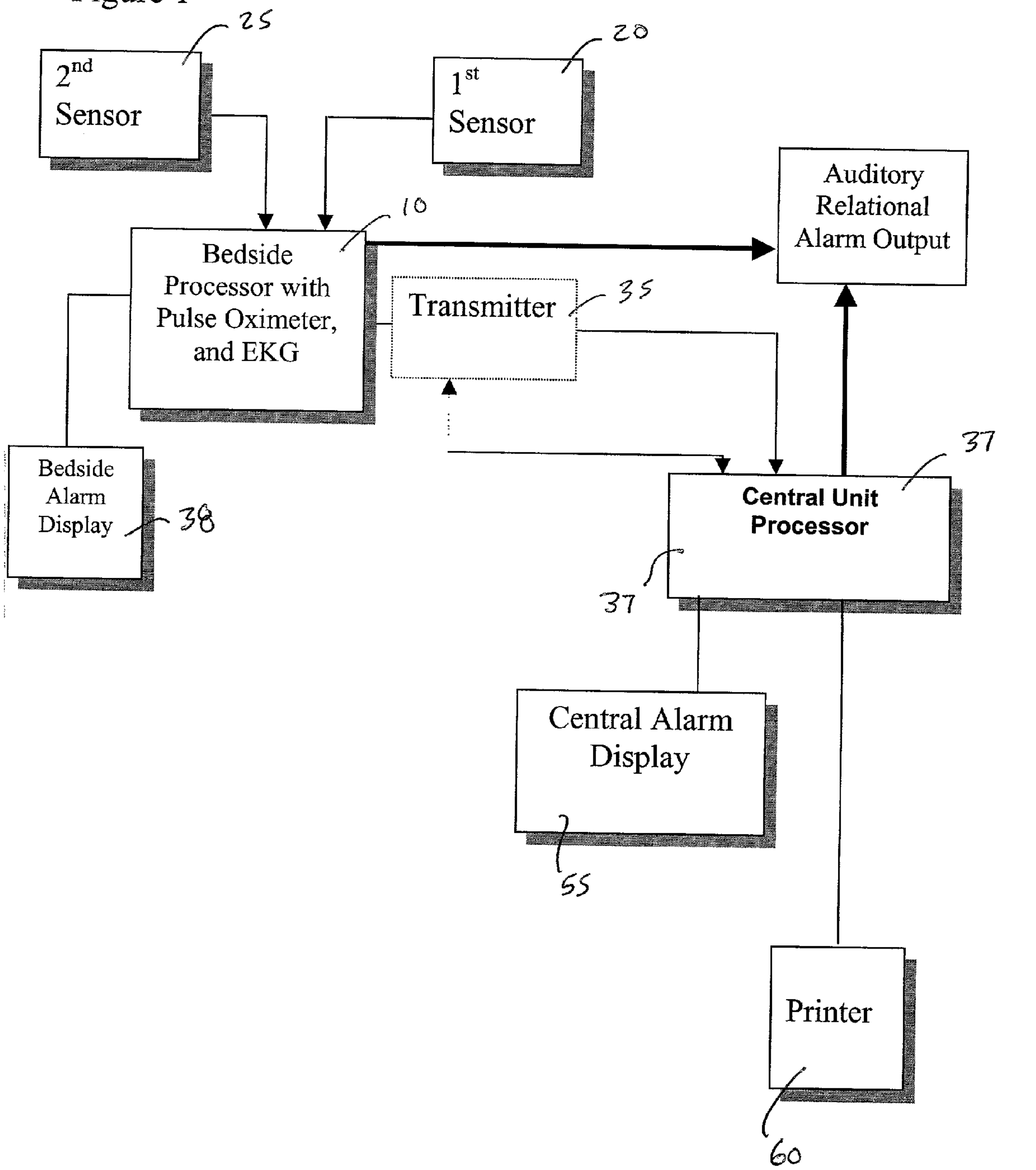


Figure 1



25
2nd Sensor
20
1st Sensor
10
Bedside Processor with Pulse Oximeter, and EKG
Auditory Relational Alarm Output
Transmitter
35
37
Central Unit Processor
37
Bedside Alarm Display
38
Central Alarm Display
55
Printer
60

Figure 2

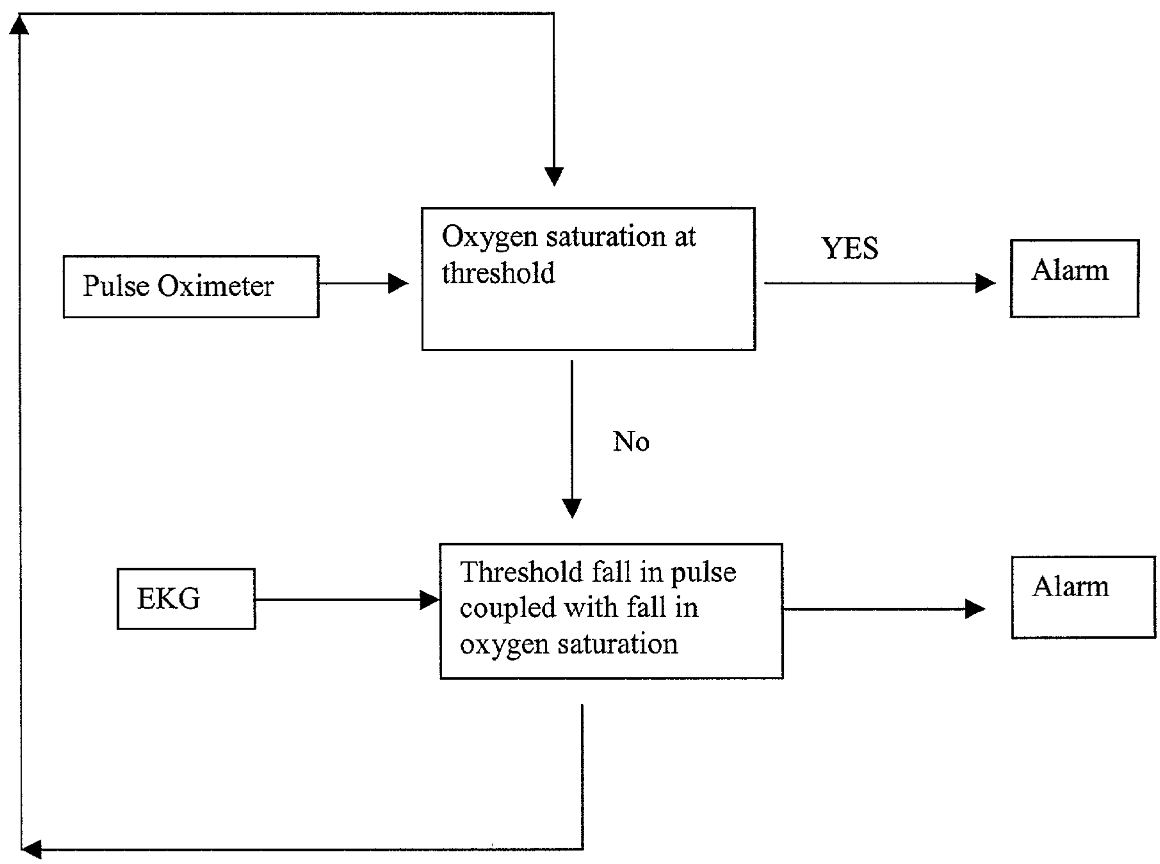

Pulse Oximeter
Oxygen saturation at threshold
YES
Alarm
No
EKG
Threshold fall in pulse coupled with fall in oxygen saturation
Alarm

Figure 3

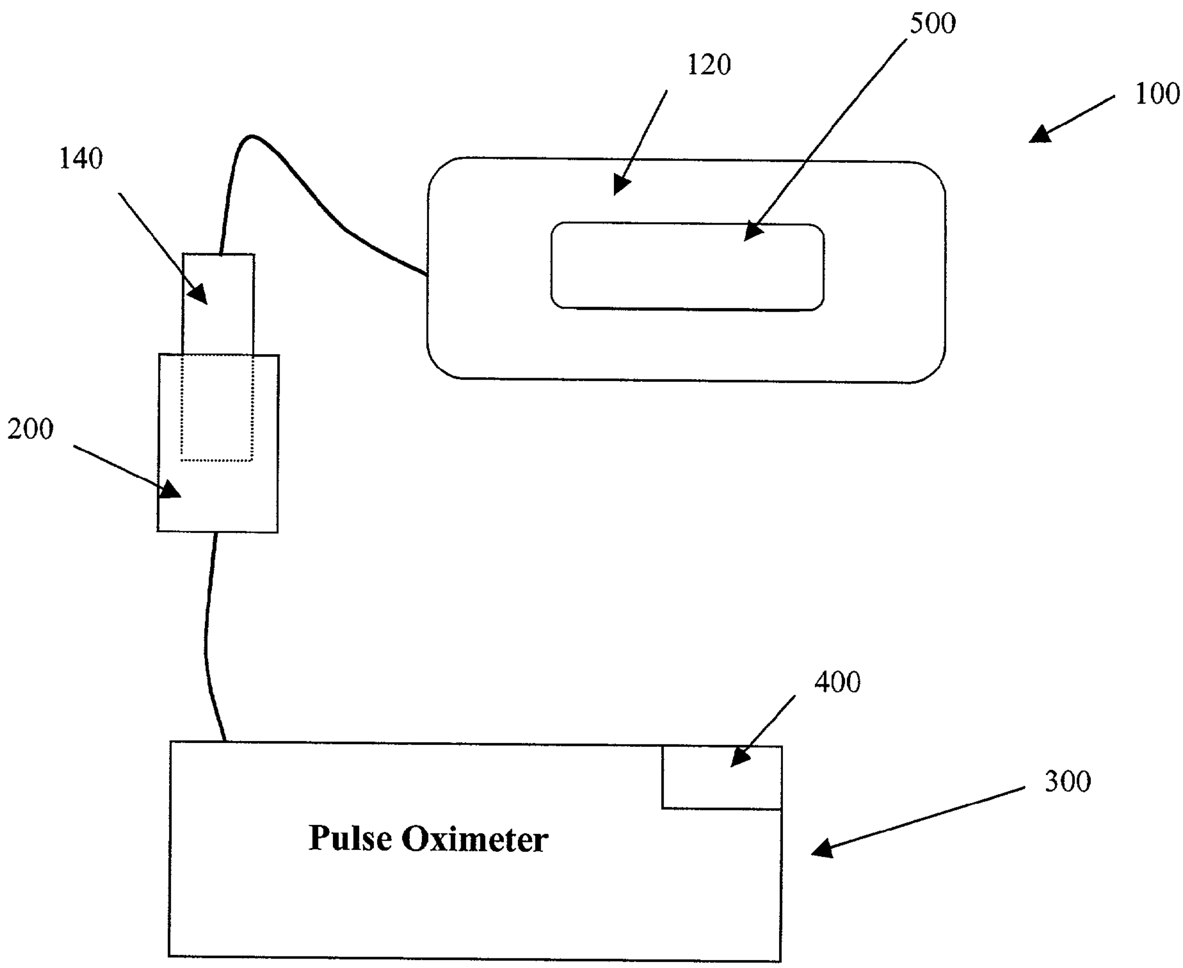
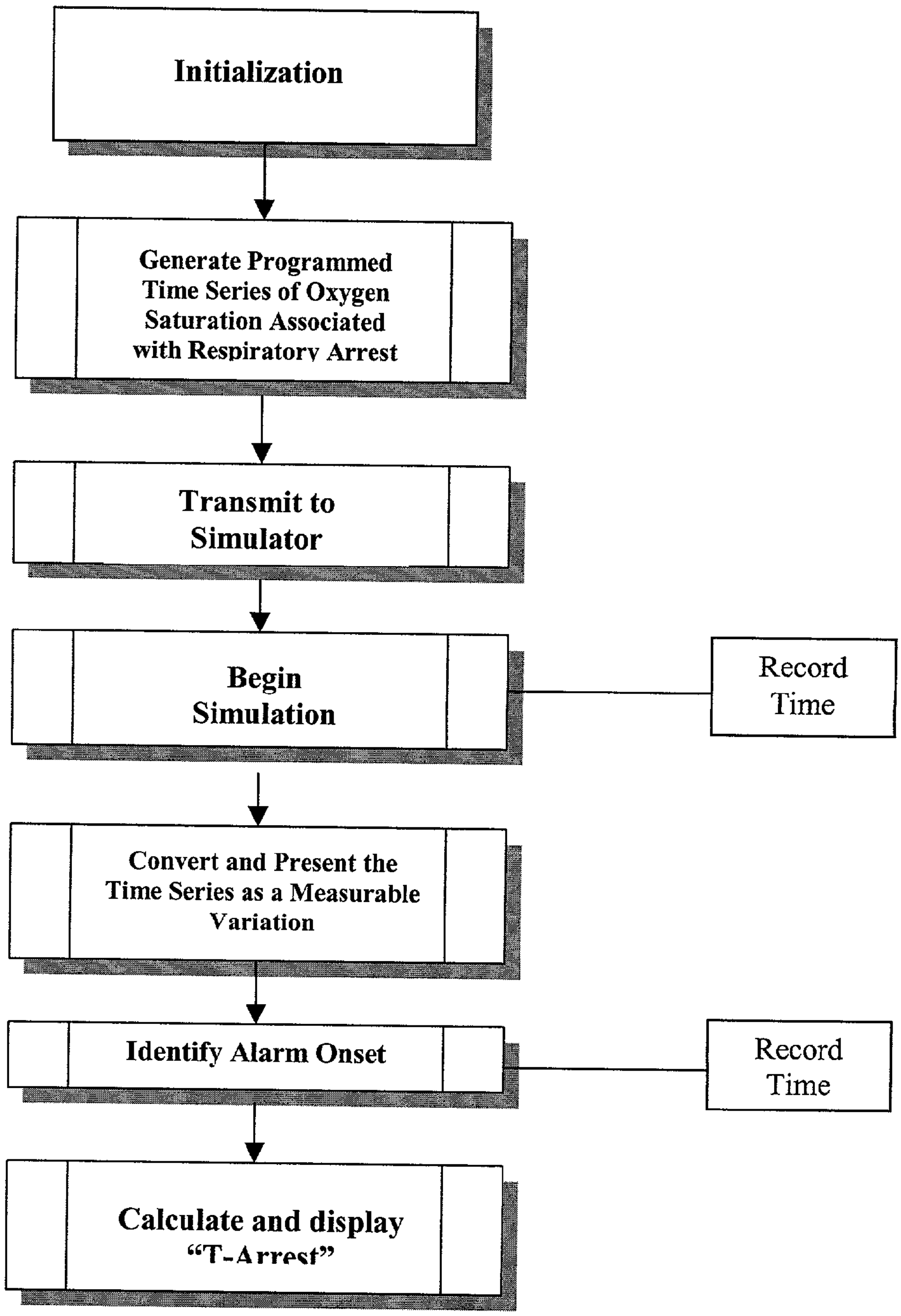


Figure 4


Initialization
Generate Programmed Time Series of Oxygen Saturation Associated with Respiratory Arrest
Transmit to Simulator
Begin Simulation
Record Time
Convert and Present the Time Series as a Measurable Variation
Identify Alarm Onset
Record Time
Calculate and display "T-Arrest"

PULSE OXIMETRY RELATIONAL ALARM SYSTEM FOR EARLY RECOGNITION OF INSTABILITY AND CATASTROPHIC OCCURRENCES

[0001] This application claims priority of a provisional application No. 60,295,484, which is incorporated by reference in its entirety as if completely disclosed herein. This application is a CIP of co pending application entitled "Centralized hospital monitoring system for automatically detection of upper airway instability and for preventing and aborting adverse drug reactions" filed May 17, 2002, which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] This application relates to improved alarm systems for oximetry and to methods of relational signal processing to enhance the specificity and timeliness of the alarms of pulse oximeters.

BACKGROUND AND SUMMARY OF THE INVENTION

[0003] Delay in recognition of respiratory instability and and/or arrest is a very common cause of unexpected death in the US hospitals. Many adverse reactions to medication and complications of surgery cause death by inducing respiratory arrest, which must be recognized early if death is to be reasonably prevented. In addition most serious diseases, such as, for example, stroke, pneumonia, blood born infections and urinary infections ultimately cause death by progression to respiratory arrest and this progression can occur very suddenly. The period of respiratory instability preceding respiratory arrest is highly variable ranging from more than 24 hours to less than a minute. Respiratory instability is painless and generally causes shortness of breath, which is often discounted by hospital personnel since this symptom is so common patients in the hospital. For these reasons the significance of the warning symptoms and signs of impending respiratory arrest are often missed by physicians and nurses since the symptoms are thought to simply be due to, for example, anxiety, postoperative pain, or fever.

[0004] It has long been known that, if patient survival is to be reasonably achieved, respiratory arrest must be reversed very quickly—before it progresses to cardiac arrest. In many cases respiratory arrest can be readily reversed and the patient stabilized by a simple bag and mask or even simple mouth to mouth resuscitation. However, once respiratory arrest induces cardiac arrest chest compressions and cardiopulmonary resuscitation becomes necessary and the success of such resuscitation in this setting is very low. The progression of respiratory arrest to cardiac arrest is perhaps best termed as a state of "dual (oxygen depletion) arrest".

[0005] To compare the significance of dual arrest it is important to contrast the process of sudden cardiac arrest as the primary event with that of a sudden primary respiratory arrest. In contrast with the dual arrest state described above, oxygen stores in arteries, veins, and lungs are retained after a sudden cardiac arrest. If the heart can be restarted (which can often be achieved within seconds by defibrillation) these oxygen stores are immediately available to restore oxygen to the brain and heart muscle and normal ventilation generally spontaneously returns. If on the other hand a respiratory arrest is the initial event, the body oxygen stores are depleted as the heart pumps the remaining oxygen stores to keep the brain and heart muscle alive after the cessation of breathing. (The heart rate generally slows during this period to reduce the use of oxygen be the heart muscle). When the oxygen stores are depleted the heart muscle stops contracting or cardiac electrical instability develops producing a secondary cardiac arrest the state of dual arrest. Upon progression to the state of dual arrest the restarting of only one system (heart or lungs) will not induce survival. Both must be restarted and this takes much more time and is much less successful. For example once dual arrest occurs, the simple restarting of the heart (as with defibrillation), will be generally unsuccessful (and useless in any regard), since the oxygen within the body has been depleted and the pumping of blood will not restore oxygen to the brain or heart muscle or restore spontaneous breathing (as would occur if the cardiac arrest was primary). In addition after dual arrest has occurred ventilating the simple ventilation of the patient, which might have easily saved the life of the patient, only seconds earlier will now be useless if not combined with complicated and often poorly successful cardiac resuscitation maneuvers.

[0006] Patients who are pregnant, obese, or have heart or lung disease may have lower oxygen stores at the time of the respiratory arrest. This means that depletion and progression to dual arrest can occur very rapidly in these patients. To understand the critical limitation of time between the onset of respiratory arrest and the development of dual arrest due to oxygen depletion in the real world, consider the case of respiratory arrest (as, for example, due to an adverse drug reaction) of a mother at near term pregnancy. After the respiratory arrest both the baby and the mother are rapidly depleting the mother's oxygen stores (which is already low due to the reduced size of the lungs due to size of the full term baby). Both the low oxygen stores and the more rapid depletion of those stores can greatly shorten the time to dual arrest, an occurrence which, if not prevented by timely ventilation, would likely result in death of both the mother and the baby. Here it can be seen that the time between the onset of the respiratory arrest and the sounding of the alarm is pivotal toward determining whether the mother and baby can be saved by simple ventilation or subjected to complex and commonly unsuccessful CPR.

[0007] Upon the recognition that it was actually respiratory arrest, which was the major leading cause of unexpected death in the hospital, the monitoring companies began to enhance electrocardiographic (EKG) monitors by combining them with pulse oximetry so both adverse cardiac events and adverse respiratory events could be identified. Today, telemetry and bedside monitors with both pulse oximetery and EKG are in wide use on hospital wards as early warning devices. Unfortunately while the alarm systems of the EKG components of the multimode monitors are excellent for immediately identifying cardiac arrest, the alarms of the incorporated pulse oximeters are very poorly suited for early identification of respiratory arrest, and in the present art these devices provide a false sense of security because they alarm in response to a respiratory arrest only after a prolonged delay—a point wherein progression to dual arrest is very near. For these reasons, a patient experiencing a respiratory arrest on a telemetry ward in US hospitals today, even though monitored by combined telemetry EKG and pulse oximetry, has a high probability of progressing to dual arrest before simple respiratory arrest is identified and reversed.

[0008] The occurrence of important delays in oximeter detection of critical clinical events has been known for many years (see "Delayed detection of hypoxic events by pulse oximeters: computer simulations", Verhoeff F, Sykes M K. Anaesthesia February 1990; 45(2):103-9). One of the factors contributing to this delay has been the high false alarm rate of pulse oximeters. Pulse oximeters have traditionally produced an output, which can be affected by motion and other sources of artifact. U.S. Pat. No. 6,206,830 entitled "signal processing apparatus and method", the contents of which is incorporated by reference as if completely disclosed herein, provides background for some of the deficiencies associated with the present art of monitoring patients using pulse oximetry. To address these deficiencies, in the present art, the output signal is subjected to a wide range of signal processing including different filters such as low pass and averaging filters as well as adaptive filters. These filters, while reducing false alarms, may significantly decrease the dynamic response of the oximeter so that the true alarm may be delayed. Since, as noted, pulse oximeters are now being coupled with telemetry units for transmission of the oxygen saturation values to a central station the transmission may be intermittent (for example to save battery power) with the central station updated only at predetermined intervals. This can result in an additional delay. Each of these delays can be additive and this can seriously reduce the remaining time available to hospital personnel after the alarm to reverse the respiratory arrest before the onset of the much less reversible dual arrest state.

[0009] Since thousands of patients die every year from delayed recognition of respiratory arrest, scientists in the field of pulse oximetry have been working hard to improve patient monitoring in this environment. Much of the work has focused on the adverse effect induced by excessive false alarms on the timeliness of the response to a true alarm. In response manufacturers have provided selectable delays with some pulse oximeters to reduce the number of false alarms, but the disclosed methods reduce false alarms by producing a further delay in response to true alarms. U.S. Pat. No. 5,865,763 entitled, "Method and apparatus for nuisance alarm reductions" (the disclosure of which is incorporated by reference as if completely disclosed herein) shows one such selectable delay system and provides additional background for the present invention.

[0010] However, since the delay in the disclosed method and apparatus which mitigates false alarms also results in a delay in alarm response to a respiratory arrest, this new alarm system reduces false alarms at the expense of providing less time to prevent progression to the highly fatal state of dual arrest.

[0011] When monitored by the basic conventional hospital montage (which includes electrocardiogram, pulse oximetry, and chest wall impedance, EKG), the human physiologic system produces a large array of highly interactive time series outputs, the dynamic relational configurations of which have substantial relevance when monitored over both brief and long time intervals and which can be used to generate improved alarm response.

[0012] Critical illness is one example of a complex dynamic timed process characterized by a plurality of interactive primary and compensatory outputs. When human physiologic stability is under threat, it is maintained by a complex array of interactive physiologic systems, which control the critical time dependent process of oxygen delivery to the organism. Each system (e.g. respiratory, cardiac or vascular) has multiple biochemical and/or mechanical controls, which operate together in a predictable manner to optimize oxygen delivery under conditions of threat. For example, a respiratory arrest (as with breath holding) causes a fall in heart rate to protect the heart muscle from the fall in oxygen. In addition to the basic control of a single system, other systems interact with the originally affected system to producing a predictable pattern of response.

[0013] Each system generally also has a plurality of predicable compensation responses to adjust for pathologic alteration or injury to the system and these responses interact between systems. For example the development of infectious injury to the lung will generally result in an increase in respiratory rate to compensate for the loss of functional surface area. This increase in ventilation rate can then induce a synergistic increase in both stroke volume and heart rate.

[0014] Finally a pathologic process altering one system will generally also induce an alteration in one or more other systems and these processes are all time dependent. Sub acute or acute life threatening conditions such as sepsis, pulmonary embolism, or hemorrhage generally affect the systems in cascades or predictable sequences which may have a time course range from as little as 20 seconds or more than 72 hours. For example, the brief development of airway collapse induces a fall in oxygen saturation and a fall in heart rate. If the patient survives to arouse this causes a compensatory hyperventilation response, which causes a rise in heart rate and all of this may occur in over as little as 20-30 seconds alternately if they fail to arouse (as due to an adverse drug reaction) the respiratory arrest progressive fall in oxygen coupled with a fall in heart rate may progress to the state of dual arrest. The progression to this state may be greatly accelerated by the presence of poor ventricular function, electrical or conduction instability, or coronary disease. An infection, on the other hand, has a more prolonged time course often over a course of 48-72 hours—inducing a rise in respiration rate, a rise in heart rate, and then a progressive fall in oxygen saturation and finally respiratory arrest and a terminal fall in heart rate. As effective physiology compensation becomes exhausted, the final event of respiratory failure and arrest can occur precipitously during the night (when hospital staffing is low) thereby surprising the hospital staff with, what appears to be a sudden respiratory arrest.

[0015] As discussed in detail below, the present inventor recognized that precipitous pathophysiologic catastrophic events such as respiratory arrest are generally preceded by at least a brief episode of instability, which falls within a rage of definable patterns. He further recognized that both the instability and the catastrophic occurrence involves multiple interactive organ systems which produce definable relational patterns indicative of the occurrence which could then be exploited using a microprocessor to more timely recognize the adverse occurrence. Upon this realization he developed a system and method which provided signal integration and/or comparison of multiple signals, and in particular the patterns defined by multiple signals to define alarm threshold provided a better means to improve timely response to a catastrophic occurrences such as a respiratory arrest. According to the preset invention, the recognition of combined deviation of at least one parameter in combination with a fall in oxygen saturation (especially if the other parameter is identified and/or confirmed by another method such as EKG) can be used to generate an earlier alarm and a more reliable alarm.

[0016] As discussed in co pending application "Centralized hospital monitoring system for automatically detecting upper airway instability . . . ", filed May 17, 2002 (Which is incorporated by reference in its entirety, as if completely disclosed herein), and assigned to the present inventor, during health and disease, organs have a basal state (such a diastole, or functional residual capacity) and a variation (a reciprocation), away from, and back to, that basic state. At the organ level a physiologic control system, which can be anatomic, electrical, or chemical attempts to maintain normal ranges of the basal state and induces return toward the basal state. At higher levels a general basal state of the entire organism, and the interactive collective basal state of each organ, is generally maintained by a combination of interactive chemical, neural, and anatomic control. Upon variation from the basal state the physiologic control system will attempt to reverse the variation thereby producing reciprocation. The variation produces a compensatory response, which comprises a "companion reciprocation" which can be recognized by the processor and which improves the specificity of the recognition of the primary reciprocation. It can be seen that during very severe disease the attempt to achieve reversal may be unsuccessful so that reciprocations have the characteristic of being complete or incomplete. Interactive companion reciprocations operative from the cellular level to the organism level and exist across the entire range of time series scales and represent the fundamental link between the time series output of an organ or organism and the characterization of the operative control systems controlling that organ or organism, and the pathophysiologic process impacting the organ or organism.

[0017] As described in detail in provisional application Nos. 60/291,687 and 60/291,691 (the contents of each of which are incorporated by reference as if completely disclosed herein), the present inventor recognized that the onset of the development of a catastrophic event represents the onset of a unique and critical relational time series of multiple signals (such as pulse rate, respiratory rate, and oxygen saturation) which is best considered as a relational process and tracked in close detail to generate a more specific output such as an alarm and so that the physician or nurse arriving to respond to the alarm can be immediately be provided with an interpreted output of the evolution of all of the monitored interactive parameters upon the onset of the occurrence which generated the alarm. The value of a monitoring device as a early warning system is therefore direct and close function of its ability to timely alarm in response to the actual onset of the occurrence of a precipitous life threatening event rather than the timeliness of its response to the occurrence of one or more threshold breaches along a single parameter (such as oxygen saturation). This is distinct from traditional thinking with respect to oximetry (see U.S. Pat. No. 5,865,763) where the focus has been to define the alarm either as a simple function of the occurrence of one or more crossings of a particular threshold value (such as an oxygen saturation below 85-90%) or as a function of the occurrence of a cumulative magnitude of values below a simple threshold. In fact the controversy within the standards committee of the FDA for oximetry alarm guidelines has been focused not defining the relationship of the alarm response to the relational outputs of a catastrophic occurrence, but rather upon defining which one-dimensional alarm warning threshold value of oxygen saturation should be uses (such as below 90% or below 85%). Such controversy misses the point, since, in the presence of precipitous catastrophic occurrence is not a given arbitrary threshold alarm value which is critical to functional survival but rather it is the value of time between the onset of the catastrophic event and the onset of the alarm which is best defined by the relational evolution of multiple parameters.

[0018] The present inventor recognized physicians, manufacturers, and hospitals have had a long unfulfilled need for an apparatus and method to alarm in response to the dynamic, real world pathophysiologic occurrences.

[0019] The present invention comprises a method and apparatus for providing an alarm based on a relational conformation of a plurality of time series and can include a pulse oximeter based microprocessor alarm system for the recognition of specific dynamic patterns of interaction between a plurality of corresponding and related time series, the system comprising a processor, the processor programmed to; process a first time series to produce to identify a first primary threshold breach based on said first time series, process at least a second time series, compare at least a portion of said first time series to at least said second time series to produce a comparison result, identify a relationship between said first time series and said second time series to identify a relational threshold breach, output an alarm based on at least one of said primary and said relational threshold breaches. The first time series is preferably oxygen saturation and the second time series can be pulse. Alternatively, the first time series can be the oxygen saturation of arterial blood and the second time series can be the respiration rate and or amplitude or a derivative of both the rate and amplitude (as by chest wall impedance). The relational breach can be a fall in oxygen saturation coupled with a fall in pulse. Another relational breach can be a fall in oxygen saturation coupled to a rise in respiration rate.

[0020] In one embodiment, the physician can select from a menu, which signals are to be included in the alarm response so that the alarm is tailored to the patient. According to the present invention, the system includes the conventional threshold based alarms to provide a floor of protection with the relational alarm system of the present invention included to provide more timely response upon the occurrence of instability or a precipitous life-threatening event such as respiratory arrest.

[0021] It is the purpose the present invention to provide a method and apparatus for providing dynamic alarm function of oximeters in response to precipitous catastrophic occurrences.

[0022] It is further the purpose of the present invention to provide a method and apparatus for promoting the sale of improved oximeters, which provide enhanced early warning characteristics, features, and functionality.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] **FIG. 1** shows a schematic of a relational alarm system according to the present invention.

[0024] FIG. 2 shows a schematic of the processing method for analyzing a plurality of time series to provide earlier recognition of a pattern indicative of a particular a respiratory arrest according to the present invention and defining the time onset of an alarm of a pulse oximeter.

[0025] FIG. 3 shows a schematic of one preferred embodiment of the oximeter testing apparatus.

[0026] FIG. 4 shows one presently preferred processing method for testing of an oximetery systems ability to timely warn of a real world catastrophic occurrence using a respiratory arrest simulation

DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

[0027] FIG. 1 shows a relational alarm system for real time detection of a broad range of patterns and instabilities (as described in the aforementioned co pending patent application). The system includes a portable bedside monitor 5, which incorporates a pulse oximeter having at least a first sensor 20 and a electrocardiogram or other monitor including at least a second sensor 25. The system includes a transmitter 35 to a central processing unit 37. The bedside processor 5 preferably includes an output screen 38, which provides the nurse with a bedside indication of the sensor output. The central unit 37 preferably includes as output screen 55 and printer 60 for generating a hard copy for physician interpretation. According to present invention, and as discussed in detail in the aforementioned patent application, the system provides recognition and alarm of catastrophic occurrences based on analysis of relational outputs of a plurality of time series thereby allowing earlier and more specific recognition of respiratory arrest, airway instability, and complications related to such instability, and pathophysiologic divergence.

[0028] FIG. 2 shows a processing method for the relational alarm system. In one preferred embodiment the oxygen saturation is monitored along with the pulse rate (which is preferably derived from another sensor so that the same artifact is less likely to affect both sensors. In an example, as is conventional, if the processor identifies a fall in oxygen saturation or pulse that meets threshold (for example 85% and 50 respectively, the alarm sounds. However according to the present invention, if on the other hand the primary threshold is not reached but a secondary threshold is reached (for example a fall of 5% within 45 seconds) and there is a combined fall in oxygen saturation in association with a concurrent fall in heart rate (for example a fall of 8 or more beats per minute within 45 seconds) wherein the fall in heart rate developed in relation to the fall in oxygen saturation (immediately prior to, as for example 30 seconds or less), at the same time, or immediately thereafter) the alarm sounds indicating a relational output suggestive of an adverse event and that relational output is provided for over reading by the hospital worker. Here, it can be seen upon the teaching of the present invention that in the presence of adverse relational outputs, delaying the alarm until the primary 85% threshold breach is reached is not warranted or safe.

[0029] Upon this teaching those skilled in the art will recognize that many alternative relational outputs can be combined and analyzed along with oximetry (as by the time series analysis methods described in the aforementioned patent applications to the present inventor) to provide improved and more specific alarms and these are included within the scope of this teaching. For example a menu system for identifying the relational parameters to be including in the alarm could be provided. These can be selected by the user or coded in advance as set of alarm montages for application to a specific group of patients (e.g. based on the entered patient activity classification such as ambulatory, restless, quiet, comatose). The nurse could select specific relationships, which he or she desires for recognition and warning by the processor. According to the present invention the relational alarms could be customized to identify instability as well as a life-threatening occurrence. One example of instability warning would be an the selection of an alarm triggered by a relational pattern identified by the processor defined by a fall in oxygen saturation of X (say greater than or equal to 8%) coupled with a rise in respiration rate of Y (say 50% or more) lasting for at least Z (say 5-10 minutes). A relational pattern of signals falling within this range is highly indicative of respiratory instability. Accordingly, it is one of the express purposes of the present invention to provide for physicians and nurses, using these different warning relationships and patterns, considerably more functional and discretionary surveillance over different groups of patients.

[0030] FIG. 3 shows one preferred embodiment of the oximeter testing apparatus 10, which can be used with a conventional oximeter or with a relational alarm based system of the present invention. The testing system includes a processor 12 in connection with a dynamic simulator 14 (which can be shaped to be received into a conventional finger probe) for interfacing with the probe 20 of an oximeter 30. A processor 12 controls the output of the simulator 14 according to the process of FIG. 2. The processor 12 is programmed to simulate the time series of arterial oxygen saturation and one or more additional parameters, which are generated in association with the occurrence of a precipitous apnea or respiratory arrest as from functional residual capacity. The programmed time series can be predicted by known formulas or, the time series of oxygen saturation and pulse (if also included) can be defined by or calculated from published clinical trials. In the preferred embodiment the simulated occurrence is a complete respiratory arrest occurring precipitously with the lung volume at functional residual capacity and at room air (21% oxygen) at the time of onset of the arrest. The dynamic oxygen saturation time series simulation for this occurrence can be, for example, the known delay and subsequent shape and slope of fall of the oxygen saturation time series (as can be calculated using known formulas for conversion of partial pressure of oxygen time series to oxygen saturation time series) as determined with breath holding clinical trials. (An example of such a clinical trial was published in Chest in 1996 entitled. "Arterial Blood Gas Changes during Breath-Holding from Functional Residual Capacity" by Sasse et.al.) The Severinghaus equation, or other formula, can be used to calculate the time series of oxygen saturations from the PaO2, PH, and PaCO2 values from clinical trials such as the one above which publish only the blood gas values. This can be coupled with the know range of falls in pulse if a relational monitor, according to the present invention is being tested

[0031] The processor is programmed to output a baseline saturation (such as 97-100%) and then to begin (automatically or on command) the simulation of the precipitous respiratory arrest. The processor sets the clock at the onset of the simulated respiratory arrest. The processor is further programmed to then output a time series of oxygen saturation values with the predicted real time fall in oxygen saturation according to that predicted for such an event to the simulator for presentation to the probe. The time series of oxygen saturation values from the processor mirrors those calculated for the article noted or can be another time series, which mirrors the dynamic changes of oxygen saturation during a particular type of critical illness. In one preferred embodiment, an audio sensor is provided in connection with the processor, the sensor is responsive to the high frequency sound produced by the oximeter alarm. Upon the occurrence of the alarm, the sensor outputs an indication of the alarm occurrence to the processor, which records the time of onset of the alarm occurrence. Alternatively the time of onset of the alarm occurrence can be input by hand or automatically by connecting the processor of the oximeter and the processor of the testing device. The difference between the time of onset of the simulation of the respiratory arrest and onset of the alarm occurrence is calculated by the processor and outputted as the "TA" or "T-Arrest" value (given in seconds).

[**0032**] According to the present invention the "T-Arrest" is defined as: The time from the onset of a standardized respiratory arrest simulation to the onset of the alarm. This is a single number used to provide evidence of the performance of the oximeter as an early warning device. In one embodiment the T-Arrest is determined during motion and is given as the "TAM" or the "T-Arrest (Motion)". According to the present invention, oximeters will be marketed by publishing the TA and the TAM which (like the simple horsepower value in an automobile) will be used to determine performance. It is anticipated that, the present invention can be used by hospitals to test their existing oximeters and to test new devices before purchase. In the preferred embodiment the audio sensor has a threshold value equal to a decibel level, which is readily heard and recognized by a human ear.

[**0033**] If preferred the oximeter testing system can be incorporated into the oximeter as a self-testing method or process, which may, for example be initiated by keying in a "simulate physiology" button on the oximeter, which will then run an internal simulation and report the T-arrest. The menu could include a range of simulations, for example a time series with the alveolar oxygen at 21% at the onset of arrest in an adult, and then another with the alveolar oxygen at 40%, and a third which simulates a cardiac arrest with loss of the plethesmographic pulse, a fourth which simulates a respiratory arrest in a child or neonate. These internal simulations can be used for teaching purposes and can combine additional inputs such as pulse rate to test relational alarm features if provided. In an alternative embodiment the menu can include the selection of the inspired oxygen level and the occurrence of a specific level of ventilation (minute ventilation) and dead space.

[**0034**] Alternative configurations of the simulator can included include the addition of a transmitter for transmitting the simulated oxygen saturation output from the processor to a receiver of a separate simulator for interfacing with the probe of an oximeter at a remote location such as a patient's room. Hospitals can position a given oximeter at a bedside and the alarm testing device at the nurses station and then initiate the testing sequence to determine if the alarm will be recognized by the nurses at the station and how long after an arrest they will hear the alarm with a given oximeter (if at all). The processor can include an audio sensor **40** capable of providing an output indicative of the occurrence of an audio alarm at a specified decibel level. The processor can also include an input indicator for manually indicating when action has been taken (e.g. the time at which the beside has been reached with the ventilation equipment in hand.)

[**0035**] In operation the probe **200** is connected to the simulator **140** of the alarm testing system **100**, as in a patients room. The operator then inputs to initiate the simulation. The simulation is then initiated. The processor transmits the simulated saturation time series based on the time series predicted form the occurrence of a respiratory arrest to the simulator **140** as previously discussed and records the time of onset of the simulation. The simulator **140** presents to the probe **200** a measurable timed variation indicative of the saturation time series. When the oximeter **300** generates an auditory alarm at the specified decibel level in response to the outputs of the simulator **140**, to the site of the processor **120**, the time of onset of the alarm is recorded and the difference between the time of onset of the arrest simulation and the time of onset of the alarm is calculated and presented on the display **500**. In some situations the oximeter under test may also include a transmitter, which transmits the oxygen saturation output back to a central nursing station where the alarm will sound. Since such transmissions also may include averaging intervals or long intervals (20 seconds) between sample transmissions, the effect of this delay can also be determined by this system **100**. The system **100** can be used for spot (surprise) checks of the alarm response times in a nursing ward where all of the factors; patient physiologic delay, signal processing delay, transmission delay, alarm output delay, personnel response delay, and the delay associated with the time to reach the bedside (where the nurse inputs the endpoint), are automatically included providing a true index of the effective hospital response to an actual alarm indicative of a life threatening event.

[**0036**] It will be evident to those skilled in the art that many additional modifications may be made, and these are included within the scope of the invention.

What is claimed is:

1) A pulse oximeter based hospital microprocessor alarm system for the recognition of specific dynamic patterns of interaction between a plurality of corresponding and related time series, the system comprising a processor, the processor programmed to;

a) process a first time series to produce to identify a first primary threshold breach based on said first time series,

b) process a second time series,

c) compare at least a portion of said first time series to said second time series to produce a comparison result,

d) identify a relationship between said first time series and said second time series to identify a relational threshold breach.

e) output an alarm based on at least one of said primary and said relational threshold breaches.

2) An oximeter testing system for testing an oximeter having an alarm, said alarm defining an initial time of onset in response to a clinical adverse event, and for testing the timeliness of said time of onset in response to said clinical adverse event, the system comprising;

a) a processor programmed to:

generate an output indicative of a time series of oxygen saturation values, said output simulating the time series of oxygen saturation values associated with clinical occurrence of an adverse clinical event, said occurrence having a time of onset, and to,

calculate the difference between said time of onset of said occurrence and said time of onset of said alarm.

b) an oxygen saturation simulator for presenting said output to said oximeter, so that the delay between the onset of said occurrence and the occurrence of said alarm can be determined.

3) The system of claim 2 wherein said simulated occurrence is a respiratory arrest.

4) The system of claim 2 wherein said simulated occurrence is a respiratory arrest occurring with the lung volume at functional residual capacity at the time of onset of said occurrence.

5) The system of claim 2 wherein said simulated occurrence is a respiratory arrest occurring with the alveolar oxygen concentration at about 21% at the time of onset of said occurrence.

6) The system of claim 2 wherein said processor is programmed to identify the time of onset of said alarm of said oximeter.

7) The system of claim 2 wherein said processor is programmed to measure the difference between said time of onset of said occurrence of said clinical adverse event and the time of onset of said alarm.

8) The system of claim 2 wherein said processor is programmed to output an indication of said difference.

9) The system of claim 2 wherein said processor is programmed to output said difference.

10) The system of claim 2 wherein said oximeter includes a probe, said simulator including a member for interfacing with said probe, said member capable of presenting a secondary dynamic variation simulating a primary dynamic variation in oxygen saturation, said variation being based on said output, said processor presenting said output to said member, said member presenting said dynamic variation to said probe.

11) The system of claim 2 further including a audio sensor for automatically detecting the occurrence of said alarm.

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