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(54) **INTELLIGENT MEDICAL VIGILANCE SYSTEM**

INTELLIGENTES MEDIZINISCHES ÜBERWACHUNGSSYSTEM

SYSTEME DE SURVEILLANCE MEDICALE INTELLIGENT

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Description

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/526,612 filed December 4, 2003.

FIELD OF THE INVENTION

[0002] The present invention relates generally to monitoring systems, and more particularly has reference to intelligent medical vigilance systems used for monitoring patients, automobile drivers, or other persons whose physiological condition may undergo a change signifying a deterioration in condition, a tendency toward drowsiness, or other state that may have important consequences for that person or for others.

BACKGROUND OF THE INVENTION

[0003] Medical monitors have been in use for many years. Typically, medical monitors include patient monitors prescribed by a physician in a non-ICU setting.

[0004] While typical devices may be suitable for the particular purpose to which they address, they are not as suitable for providing an invisible "safety net" for a patient that will observe and analyze, and, only in the event of a clinically significant negative condition, notify and report the event to the care staff utilizing the hospital's existing nurse call system.

[0005] Patent application US 5,724,025 by Tavory, discloses a portable vital signs monitor including a plurality of sensors and an alarm mechanism which is designed to activate when one or more predetermined set points or combination of set points stored in the data storage is exceeded.

[0006] Patent application US 5,585,785 by Gwin et al., discloses a driver alarm with a pressure transducer attached along the circumference of the steering wheel of a vehicle to measure hand grip pressure on the wheel and sound an alarm when the pressure falls below a lower limit and when the transient behavior of the pressure signal deteriorates substantially.

[0007] The main problem with conventional medical monitors is they are designed to respond to rapidly changing situations (found, in ICUs) and thus have a high false alarm rate. Outside the intensive care unit, these monitors are not usually connected to a remote alarm, so local alarms sound, disturbing the patient, their family and friends and the workflow of the various clinicians providing care to the patient. Many attempts have been made to make alarms more meaningful.

[0008] Another problem is that standard devices require contact directly to the patient's skin or body via cables or wires. This means constraining the patient's movement to prevent disconnecting the sensors and also creates a danger of entanglement or strangulation from the cables. Additionally, these devices are relatively expensive to purchase and somewhat complex to operate, requiring a trained individual to operate property.

[0009] Thus, a need exists for simpler, less expensive and more accurate methods for noninvasive vital sign monitoring of significant negative conditions and reporting these events. This invention addresses these and other needs.

SUMMARY OF THE INTENTION

[0010] Briefly, and in general terms, the present invention involves a new and improved intelligent medical vigilance method and apparatus for providing an invisible "safety net" that observes and analyzes a person's vital signs. Only in the event of a clinically significant negative condition will the device notify and report the event to the person or the care staff of a health care facility, utilizing, for example, a hospital's existing nurse call system. In so doing, the invention extends the vigilance capability and "reach" of the hospital clinical staff so that their resources can be more effectively applied.

[0011] The present invention has many of the advantages of the medical monitors mentioned heretofore and many novel features that result in a new intelligent medical vigilance system which is not anticipated, rendered obvious, suggested, or even implied by any of the prior art medical monitors, either alone or in any combination thereof.

[0012] In a presently preferred embodiment, by way of axample and not necessarily by way of limitation, the invention generally comprises a bedside unit connected to a sensing array (placed under the patient) and to an existing hospital nurse call system via an interface. The sensing array preferably is a non-invasive piezoelectric sensing film or other similar sensing technology, with an array of sensors installed in soft padding under the bottom sheet of the patient's hospital bed. The sensing array is not directly in contact with the skin of the patient. Within the physical bedside unit are a signal processor and an alarm processor that measure the data and evaluate whether a clinically significant event is occurring.

[0013] The bedside unit is a wall-mounted unit with a display that becomes active (comes on) when an alarm condition is enabled or on command by the nurse, by touching any key. It has a number of dedicated and softkey buttons and controls for entering information, setting up specific items and interacting with the system.

[0014] The sensing array is a thin, piezoelectric film or other similar sensing technology, with an array of sensors sheathed in soft padding that is easily cleaned. It is placed in the patient's bed, under the bottom sheet (and other padding if needed), not directly in contact with the skin of the patient. It can be integrated into the mattress coverlet, if desired. The monitoring system of the present invention may also be used in chairs to monitor the state of relaxation of a subject via heart rate, blood pressure and respiration rates.

[0015] The nurse call feature is made up of hardware, software and cabling to connect to a nurse call system already installed in the hospital or care facility. The signal processor is made up of hardware and software that accepts, buffers and converts the sensor array signal from analog to digital format for subsequent processing. The alarm processor uses logic to monitor the parameter trends and determines when a negative condition is occurring. It then actuates the alarm circuitry for local and/or remote alarm. Soft alarms may be used to report adverse trends before an emergency condition arises. All alarms may interact with the existing nurse call system in the hospital.

[0016] In alternative embodiments, the intelligent medical vigilance system of the present invention can be adapted for use as a monitoring system for operators of motor vehicles, aircraft or other devices. The present invention is installed in one or more of the following regions of a motor vehicle: the seat, seatback, headrest, steering wheel, driving jacket, or a driving cap. One or more sensors may be located in each general location to provide for improved feedback. The vehicle operator may also carry a wrist attachment or a necklace with built in sensors.

[0017] The sensors in the vehicle transmit information about the patient to a central processor built into the vehicle via hardwiring or wireless technology. The processor analyzes the incoming information and outputs data as needed. The vigilance system can be used to alert drivers to approaching sleep states or other potentially hazardous physical conditions in order to reduce accidents. The sensors measure heart rate, respiration rate and movement of the vehicle operator.

[0018] Background noise signals are actively cancelled out to provide an accurate reading of the patients heart rate, respiration rate and blood pressure. This cancellation allows the monitoring system to operate effectively in high background noise environments.

[0019] Trend information is also recorded and available for study.

[0020] The present invention overcomes many of the shortcomings of the prior art devices.

[0021] In a preferred embodiment, the present invention provides an intelligent medical vigilance system for providing an invisible "safety net" for the patient that will observe and analyze, and, only in the event of a clinically significant negative condition, notify and report the event to the care staff utilising the hospital's existing nurse call system.

[0022] In a further preferred embodiment, the invention provides an intelligent medical vigilance system that observes (monitors) multiple physiological signals without direct skin contact.

[0023] In yet a further embodiment, the invention provides an intelligent medical vigilance system that analyzes the information to determine whether the parameters are within normal limits or are tending to go in a clinically negative direction.

[0024] In a further aspect, the invention provides an intelligent medical vigilance system that reports the physiological parameters and provides a trend of them over time.

[0025] In yet a further aspect, the invention provides an intelligent medial vigilance system that notifies the nursing care staff when a consistently negative situation is detected via the existing nurse call system used in the facility.

[0026] In still a further aspect, the invention provides an intelligent medical vigilance system that persistently reminds nursing of continued violations or worsening situation until interventions are successful. This aspect provides an intelligent medical vigilance system that extends the vigilance capability and "reach" of the busy clinical staff so they can spend time where it has the best clinical effect.

[0027] In another aspect, the invention provides a sensor system within vehicles that alerts operators to dangerous physiological conditions that would impair the operator's ability to operate equipment safely.

[0028] These and other advantages of the invention will become more apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the features of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029]

Figure 1 is a diagram of the vigilance monitoring system of the present invention.

Figure 2 is a block diagram of the system functions.

Figure 3 is a diagram showing progression from normal patient condition to negative event and nurse response.

Figure 4 is a time plot of multiple parameters, showing various parameter violations and alarm logic.

Figure 5 is multiple parameter alarm table, showing alarm logic.

Figure 6 is a diagram showing various configurations of sensors in a vehicle.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0030] Figure 1 illustrates an intelligent medical vigilance system 1, which comprises a bedside unit 3 connected to a sensing array 5 (placed under the patient) and also to an existing hospital call system 7 via an interface 9. Within the physical bedside unit 3 are a signal processor and an alarm processor that measure the data

and evaluate whether a clinically significant event is occurring. The present invention can also be used as a monitoring system in vehicles.

[0031] The bedside unit 3 is a wall-mounted unit with a display 9 that becomes active (comes on) when an alarm condition is enabled or on command by the nurse, by touching any key. It has a number of dedicated and softkey buttons and controls for entering information, setting up specific items and interacting with the system.

[0032] While various types of sensors can be used, it is preferred that the sensing array 5 be in the form of a thin, piezoelectric film sensing array sheathed in soft padding that is easily cleaned. It is placed in the patient's bed 11, under the bottom sheet (and other padding if needed), not directly in contact with the skin of the patient. The sensing array 5 may be incorporated into soft padding under the bottom sheet of a patient's bed.

[0033] The nurse call feature 7 is made up of hardware, software and cabling to connect to the nurse call system already installed in the hospital or care facility.

[0034] The signal processor is made up of hardware and software that accepts, buffers and converts the sensor array signal from analog to digital format for subsequent processing. Trend information is recorded and available for study.

[0035] The alarm processor uses logic to monitor the parameter trends and determines when a negative condition is occurring. It then actuates the alarm circuitry for local and/or remote alarm. Soft alarms may be utilized to report adverse trends before emergency situation arises.

[0036] Figure 2 shows a schematic diagram of the monitoring process of the present invention. Figure 3 is a diagram showing progression from normal patient condition to negative event and nurse response.

[0037] In all patient monitoring devices with alarms the user can set "hard" alarm limits - those high and low single-parameter limits that, when passed, will cause the alarm indication, signal and tone to be transmitted to the caregiver by any number of means. The caregiver responds to correct the situation. One problem caused by such alarms is that of false positive alarms - those alarms that sound because the set threshold is passed momentarily, but that are not associated with a clinically significant event. In order to monitor the patient closely the alarm limits may be set close to the patient's present parameter value. The closer these are set, the more likely it is that a minor actual parameter variation, patient movement or other signal "noise" will make the measured parameter surpass the set alarm limit.

[0038] Few if any alarms use any delay or additional processing other that the filtering used to compute the average of and display the parameter's value. There have been many attempts to measure the inadequacy of such simple alarms in the intensive care unit. There are also methodologies used to dolay alarming until a certain time since passage outside the range integrated with the extent of the deviation beyond the set range is exceeded.

[0039] In an intelligent vigilance monitor such as the one used in this invention, the "hard" alarm limits can be spread more widely than in conventional intensive care unit monitors. This is done because the patients being monitored may be relatively healthy and mobile compared to typical ICU patients. Because of their high activity level they exhibit a lot of variability in their measured vital parameters such as heart rate, respiratory rate, blood pressure, temperature, cardiac activity, etc. Thus, the clinician wants to watch over these patients' condition, but also wants to avoid false positive alarms that disrupt the patient care workflow and the feelings and outlook of the patient. However, the clinician is still interested in detecting negative trends in the patient so they can react quickly to treat or avoid deeper, more serious problems.

[0040] Figures 4 and 5 show the use of alarm limit pairs and algorithms. Figure 4 is a time plot of multiple parameters, showing various parameter violations and alarm logic. Figure 5 is multiple parameter alarm table, showing alarm logic.

[0041] To accomplish a balanced response, the monitor of the present invention has two or more distinct alarm limit pairs and algorithms. The purpose of the new alarm scheme is to set new thresholds within the previous "hard" limits of each parameter that will catch a patient's worsening condition prior to crossing the old single "hard" limits. This differs from just moving those limits in because these new, soft limits require that both the HR and RR values (in this example) be outside the soft limits to initiate the alarm. If either the HR or RR falls outside a hard limit, then the alarm sounds. If both the HR and RR fall outside the soft limit, but still within the hard limit, then the "soft" alarm sounds. This is best described in Figure 4.

[0042] The parameters covered by such an alarm scheme are not limited to Heart Rate and Respiratory Rate, used in this example. In addition, the sensitivity and specificity of the "hard" alarm may bo improved by using a more-complex algorithm than just "did it pass the limit?" used in many systems. This improvement could take the form of applying a number of approaches including but not limited to neural net and/or fuzzy logic.

[0043] Fuzzy logic could be applied to the limit as follows: Given one or more measurements of physiological parameters (e.g. heart rate, respiration rate, blood pressure, temperature, etc.) which require an alarm when the measurement is outside of a range (or band), a fuzzy logic type function can be defined as follows:

$A = \sum_{n=0}^{N-1} F_n(p_n)$, an alarm truth function, based on N different parameters or signals, and a signal truth function F(p) for each parameter or signal

$$F(p) = \left\{ \begin{array}{l} 1, \text{ for } p < t_{Ll} \\ > 0 \text{ for } t_{Ll} \le p \le t_{Lh} \\ 0, \text{ for } T_{Lh} < p < t_{Hl} \\ > 0, \text{ for } t_{Hl} \le p \le t_{Hh} \\ 1, \text{ for } p > t_{Hh} \end{array} \right\}$$, with the additional constraint that F(p) must be monotonically increasing for t_{Hl} <= p <= t_{Hh} and monotonically decreasing for t_{Ll} <= p <= t_{Lh}.

[0044] The sum of N different physiological fuzzy logic functions can be used to establish an alarm equation (See alarm truth function above) described further as follows: When A >= Ta, the alarm sounds, otherwise it does not. Ta is typically set to 0.5 if any weak (or soft) condition (or combination of weak conditions) is to cause an alarm. If Ta is set to 1.0 a strong alarm condition from at least one physiological parameter is required for the alarm to sound. If it is desired that the alarm only sound when Physiological parameters are at or above $t_{Hh}(n)$ (or below $t_{Ll}(n)$), then Ta can be set to N. This method can also be used when the same physiological parameter is measured by multiple means.

[0045] In the case of two measurements of the same physiological parameter, the F(p) functions would most likely be the same for each measurement and Ta could be set to 1.0 such that if either device exceeded the t_H limits, the alarm would sound. The alarm violation type (hard, soft, etc.) may be differentiated from each other or not, depending on the needs for the specific clinical application (ICU versus General Care Floor, etc.). The alarms may be set individually for each parameter as soft high and soft low or may be set by using a fixed percentage, such as 10% within the range of the hard limits for each parameter. The logic can also be extended to more than two alarms if needed.

[0046] The sensitivity of both the "hard" and "soft" limits also may be improved by delaying the alarm until the monitor determines that a signal has passed a limit for a certain length of time, such as 10 seconds. In this way, momentary changes in a signal having no clinical significance can be ignored.

[0047] Figure 6 is a diagram of the present invention installed in a vehicle. The intelligent medical vigilance system of the present invention can easily be adapted for use as a monitoring system for operators of motor vehicles, aircraft or other devices. The sensing array of the present invention is installed in one or more of the following regions of a motor vehicle: the seat 13, seatback 15, headrest 17, steering wheel 19, driving jacket 21, or a driving cap 23. One or more sensor arrays may be located in each general location to provide for improved feedback. The vehicle operator may also carry a wrist attachment 25 or a necklace 27 with built in sensor arrays.

[0048] The sensor arrays in the vehicle transmit information about the patient to a central processor 29 built into the vehicle via hardwiring 31 or wireless 33 technologies. The processor analyzes the incoming information and outputs data as needed. The vigilance system can be use to alert drivers to approaching sleep states or other potentially hazardous physical conditions in order to reduce accidents. The sensors can be configured to measure a variety of parameters, such as heart rate, respiration rate, blood pressure, temperature, cardiac output and movement of the vehicle operator. The intelligent monitoring system in vehicles uses similar alarm schemes to those in a hospital setting.

[0049] Background noise signals are actively cancelled out to provide an accurate reading of the operator's measured physiological parameters. This cancellation allows the monitoring system to operate effectively in high background noise environments.

[0050] While a particular form of the invention has been illustrated and described, it will also be apparent to those skilled in the art that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited except by the appended claims.

Claims

1. A method for monitoring the physiology of a person and providing an alarm to warn of an undesirable condition, comprising:

   placing adjacent the person a plurality of sensors (5) configured to detect physiological parameters of the person;
   detecting one or more physiological parameters of the person with said sensors (5);
   converting the detected one or more physiological parameters into signals;
   assigning an upper hard range of signal values for each physiological parameter;
   assigning a lower hard range of signal values for each physiological parameter;
   analyzing at least two of the signals over a period of time to determine in which range each signal is situated;
   the method being **characterized by** further comprising:

   assigning an upper soft range of signal values below the upper hard range for each physiological parameter, wherein the upper soft range is selected to be a predetermined downward departure from the upper hard range;
   assigning a lower soft range of signal values above the lower hard range for each physiological parameter, wherein the lower soft range is selected to be a predetermined up-

ward departure from the lower hard range;

activating an alarm when at least one signal is in a hard range, and
activating an alarm when at least two signals are in a soft range.

2. The method of claim 1, wherein activating an alarm includes activating a hard alarm when at least one signal is in a hard range, and activating a soft alarm when at least two signals are in a soft range.

3. The method of claim 1, wherein activating an alarm includes activating an alarm using fuzzy logic to assess the significance of the plurality of signals in relation to the hard and soft ranges.

4. The method of claim 1, wherein each said plurality of sensors (5) is configured to detect the same physiological parameter of the person.

5. The method of claim 1, wherein each of said plurality of sensors (5) is configured to detect multiple different physiological parameters of the person.

6. The method of claim 1, wherein the sensors (5) are configured to detect at least two physiological parameters selected from the group consisting of heart rate, respiration rate, blood pressure, temperature, motion, and noise emission.

7. The method of claim 1, wherein the ranges of signal values are assigned by a health care giver and can be selectively varied.

8. The method of claim 1, wherein the upper soft range is automatically selected to have a lower limit that is a predetermined percentage of the lower limit of the upper hard range, and the lower soft range is automatically selected to have an upper limit that is a predetermined percentage of the upper limit of the lower hard range.

9. The method of claim 1, wherein each parameter is assigned a different soft range.

10. The method of claim 1, wherein the magnitude of the upper soft range differs from the magnitude of the lower soft range.

11. The method of claim 1, further comprising
communicating an activated alarm to a health care provider through a pre-existing nurse call system within a health care facility.

12. The method of claim 1, further comprising
selecting signals in the upper ranges which are increasing in value and signals in the lower ranges which are decreasing in value;
activating an alarm when at least one said selected signals is in a hard range; and activating an alarm when at least two of said selected signals are in a soft range.

13. The method of claim 1, further comprising
applying a fuzzy logic function to each signal within a range; and
activating an alarm when the sum of the fuzzy logic functions exceed a predetermined value.

14. The method of claim 13, wherein a first predetermined value activates a soft alarm.

15. The method of claim 13, wherein a second predetermined value activates a hard alarm.

16. The method of claim 1, wherein the upper soft range is automatically selected to have a lower limit that is a fixed percentage of the lower limit of the upper hard range, and the lower soft range is automatically selected to have an upper limit that is a fixed percentage of the upper limit of the lower hard range.

17. Apparatus for monitoring the physiology of a person and providing an alarm to warn of an undesirable condition, comprising:

a plurality of sensors (5) for detecting one or more physiological parameters of the person;
a processor configured to convert each detected one or more physiological parameters into information signals; and
an alarm system in communication with the processor, the alarm system being configured to provide one or more alarms;
wherein the processor is configured to perform steps including:

receiving a designated upper hard range of signal values for each physiological parameter
receiving a designated lower hard range of signal values for each physiological parameter;
analyzing at least two of the signals over a period of time to determine in which range of values each signal is situated;
where the apparatus is **characterized by** the processor being configured to further perform the following steps:

receiving a designated upper soft range of signal values below the upper hard range for each physiological parameter;
receiving a designated lower soft range

of signal values above the lower hard range for each physiological parameter;
activating the alarm when at least one signal is in a hard range; and
activating the alarm when at least two signals are in a soft range.

18. The apparatus of claim 17 further comprising an interface (9) for connecting the alarm system to an existing nurse call system (7) in a health care facility.

19. The apparatus of claim 17, wherein the processor is housed in a bedside unit (3), for placing alongside a bed (11) for the person.

20. The apparatus of claim 19, wherein the bedside unit further comprises a display connected to the processor for displaying physiological data, the display being automatically actuated when an alarm condition occurs.

21. The apparatus of claim 19, wherein the bedside unit further comprises a display connected to a processor for displaying physiological data, the display being selectively activated by an attending health care provider.

22. The apparatus of claim 17, wherein the sensors (5) are assembled in an array enclosed within a coverlet.

23. The apparatus of claim 17, wherein the sensors (5) are disposed within bedding for the person.

24. The apparatus of claim 17, wherein the sensors (5) comprise noninvasive sensors formed of piezoelectric material.

25. The apparatus of claim 17, wherein the sensors are installed in at least one location selected from the group consisting of a vehicle seat (13), a vehicle seatback (15), a vehicle headrest (17), a vehicle steering wheel (19), a driving jacket (21), a driving cap (23), a wrist attachment (25), and a necklace (27).

26. The apparatus of claim 17, wherein the processor (29) is located in a vehicle.

27. The apparatus of claim 17, wherein the sensors transmit the detected parameters to the processor via wireless technology (33).

28. The apparatus of claim 17, wherein the alarm is configured to alert a driver of a vehicle of an approaching sleep state.

29. The apparatus of claim 17, wherein the sensors are configured to detect at least two physiological parameters selected from the group consisting of heart rate, respiration rate, blood pressure, temperature, cardiac output and movement of the person.

30. The apparatus of claim 17, wherein the processor is further configured such that activating the alarm includes activating a hard alarm when at least one signal is in a hard range, and activating a soft alarm when at least two signals are in a soft range.

31. The apparatus of claim 17, wherein the sensors are not directly in contact with the person's skin.

32. The method of claim 1, wherein activating an alarm when at least one signal is in a hard range requires that said at least one signal remain in said range for a predetermined period of time to activate said alarm.

33. The method of claim 1, wherein activating an alarm when at least two signals are in a soft range requires that said at least one of said signals remain in said range for a predetermined period of time to activate said alarm.

34. The apparatus of claim 17, wherein the sensors are placed in soft padding under the bottom sheet of the person's bed (11).

Patentansprüche

1. Verfahren zum Überwachen der Physiologie einer Person und Bereitstellen eines Warnsignals, um vor einem unerwünschten Zustand zu warnen, umfassend:

Unterbringen einer Vielzahl von Sensoren (5) nahe der Person, die ausgebildet sind, um physiologische Parameter der Person zu detektieren;
Detektieren eines oder mehrerer physiologischer Parameter der Person mit den Sensoren (5);
Umwandeln des detektierten einen oder mehrerer physiologischer Parameter in Signale;
Zuordnen eines oberen festen Bereichs von Signalwerten für jeden physiologischen Parameter;
Zuordnen eines unteren festen Bereichs von Signalwerten für jeden physiologischen Parameter;
Analysieren von mindestens zwei der Signale über einen Zeitraum, um zu bestimmen, in welchem Bereich jedes Signal liegt;
wobei das Verfahren **dadurch gekennzeichnet ist, dass** es weiterhin umfasst:

Zuordnen eines oberen schwachen Bereichs von Signalwerten unterhalb des oberen festen Bereichs für jeden physiologischen Parameter, wobei der obere schwache Bereich als eine vorher bestimmte Abweichung nach unten von dem oberen festen Bereich ausgewählt ist;
Zuordnen eines unteren schwachen Bereichs von Signalwerten oberhalb des unteren festen Bereichs für jeden physiologischen Parameter, wobei der untere schwache Bereich als eine vorher bestimmte Abweichung nach unten von dem unteren festen Bereich ausgewählt ist;
Aktivieren eines Warnsignals, wenn sich mindestens ein Signal in einem festen Bereich befindet, und
Aktivieren eines Warnsignals, wenn sich mindestens zwei Signale in einem schwachen Bereich befinden.

2. Verfahren nach Anspruch 1, wobei Aktivieren eines Warnsignals das Aktivieren eines festen Warnsignals umfasst, wenn sich mindestens ein Signal in einem festen Bereich befindet, und das Aktivieren eines schwachen Warnsignals, wenn sich mindestens zwei Signale in einem schwachen Bereich befinden.

3. Verfahren nach Anspruch 1, wobei Aktivieren eines Warnsignals das Aktivieren eines Warnsignals mittels Fuzzy-Logik umfasst, um die Bedeutung der Vielzahl von Signalen im Verhältnis zu dem festen und dem schwachen Bereich einzuschätzen.

4. Verfahren nach Anspruch 1, wobei jeder der Vielzahl von Sensoren (5) so ausgeführt ist, um den gleichen physiologischen Parameter der Person zu detektieren.

5. Verfahren nach Anspruch 1, wobei jeder der Vielzahl von Sensoren (5) so ausgeführt ist, um vielfache unterschiedliche physiologische Parameter der Person zu detektieren.

6. Verfahren nach Anspruch 1, wobei die Sensoren (5) so ausgeführt sind, dass sie mindestens zwei physiologische Parameter detektieren, die von der aus Herzfrequenz, Atmungsfrequenz, Blutdruck, Temperatur, Bewegung und Schallabstrahlung bestehenden Gruppe ausgewählt sind.

7. Verfahren nach Anspruch 1, wobei die Bereiche von Signalwerten durch einen Krankenpfleger zugeordnet werden und selektiv verändert werden können.

8. Verfahren nach Anspruch 1, wobei der obere schwache Bereich automatisch so gewählt wird, dass er eine untere Grenze besitzt, die ein vorher bestimmter Anteil der unteren Grenze des oberen festen Bereichs ist, und der untere schwache Bereich automatisch so gewählt wird, dass er eine obere Grenze besitzt, die ein vorher bestimmter Anteil der oberen Grenze des unteren festen Bereichs ist.

9. Verfahren nach Anspruch 1, wobei jeder Parameter einem anderen schwachen Bereich zugeordnet ist.

10. Verfahren nach Anspruch 1, wobei die Größe des oberen schwachen Bereichs von der Größe des unteren schwachen Bereichs abweicht.

11. Verfahren nach Anspruch 1, des Weiteren umfassend
Kommunizieren eines aktivierten Warnsignals zu einem Gesundheitsversorger über eine vorher vorhandene Krankenschwester-Rufanlage innerhalb einer Gesundheitsfürsorgeeinrichtung.

12. Verfahren nach Anspruch 1, des Weiteren umfassend
Auswählen von Signalen in den oberen Bereichen, die im Wert zunehmen, und Signalen in den unteren Bereichen, die im Wert abnehmen;
Aktivieren eines Warnsignals, wenn sich mindestens eines der ausgewählten Signale in einem festen Bereich befindet; und
Aktivieren eines Warnsignals, wenn sich mindestens zwei der ausgewählten Signale in einem schwachen Bereich befinden.

13. Verfahren nach Anspruch 1, des Weiteren umfassend
Anwenden einer Fuzzy-Logik-Funktion auf jedes Signal innerhalb eines Bereichs; und
Aktivieren eines Warnsignals, wenn die Summe der Fuzzy-Logik-Funktionen einen vorbestimmten Wert überschreitet.

14. Verfahren nach Anspruch 13, wobei ein erster vorbestimmter Wert ein schwaches Warnsignal aktiviert.

15. Verfahren nach Anspruch 13, wobei ein zweiter vorbestimmter Wert ein starkes Warnsignal aktiviert.

16. Verfahren nach Anspruch 1, wobei der obere schwache Bereich automatisch so gewählt wird, dass er eine untere Grenze besitzt, die ein feststehender Anteil der unteren Grenze des oberen festen Bereichs ist, und der untere schwache Bereich automatisch so gewählt wird, dass er eine obere Grenze besitzt, die ein feststehender Anteil der oberen Grenze des unteren festen Bereichs ist.

17. Vorrichtung zum Überwachen der Physiologie einer

Person und Bereitstellen eines Warnsignals, um vor einem unerwünschten Zustand zu warnen, umfassend:

eine Vielzahl von Sensoren (5) zum Detektieren eines oder mehrerer physiologischer Parameter der Person;
einen Prozessor, der so ausgeführt ist, um jeden detektierten einen oder mehrere physiologische Parameter in Informationssignale umzuwandeln; und
ein Warnsystem in Kommunikation mit dem Prozessor, wobei das Warnsystem so ausgeführt ist, um ein oder mehrere Warnsignale zur Verfügung zu stellen;
wobei der Prozessor so ausgeführt ist, um Schritte durchzuführen, die umfassen:

Empfangen eines bezeichneten oberen festen Bereichs von Signalwerten für jeden physiologischen Parameter,
Empfangen eines bezeichneten unteren festen Bereichs von Signalwerten für jeden physiologischen Parameter,
Analysieren mindestens zwei der Signale über einen Zeitraum zum Bestimmen, in welchem Bereich von Werten jedes Signal liegt;
wobei die Vorrichtung **dadurch gekennzeichnet ist, dass** der Prozessor so ausgeführt ist, um des Weiteren die folgenden Schritte durchzuführen:

Empfangen eines bezeichneten oberen schwachen Bereichs von Signalwerten unterhalb des oberen festen Bereichs für jeden physiologischen Parameter;
Empfangen eines bezeichneten unteren schwachen Bereichs von Signalwerten oberhalb des unteren festen Bereichs für jeden physiologischen Parameter;
Aktivieren des Warnsignals, wenn sich mindestens ein Signal in einem festen Bereich befindet; und
Aktivieren des Warnsignals, wenn sich mindestens zwei Signale in einem schwachen Bereich befinden.

18. Vorrichtung nach Anspruch 17, des Weiteren umfassend eine Schnittstelle (9) zum Verbinden des Warnsystems mit einer vorhandenen Krankenschwester-Rufanlage (7) in einer Gesundheitsfürsorgeeinrichtung.

19. Vorrichtung nach Anspruch 17, wobei der Prozessor in einer bettseitigen Einheit (3) aufgenommen ist, um ihn für die Person neben ein Bett (11) zu stellen.

20. Vorrichtung nach Anspruch 19, wobei die bettseitige Einheit des Weiteren ein Display aufweist, das mit dem Prozessor zur Anzeige von physiologischen Daten verbunden ist, wobei das Display automatisch ausgelöst wird, wenn ein Alarmzustand auftritt.

21. Vorrichtung nach Anspruch 19, wobei die bettseitige Einheit des Weiteren ein Display aufweist, das mit einem Prozessor zur Anzeige von physiologischen Daten verbunden ist, wobei das Display durch einen pflegenden Gesundheitsversorger selektiv aktiviert wird.

22. Vorrichtung nach Anspruch 17, wobei die Sensoren (5) in einer Anordnung zusammengebaut sind, die in einer Tagesdecke eingeschlossen ist.

23. Vorrichtung nach Anspruch 17, wobei die Sensoren (5) innerhalb des Bettzeugs für die Person angeordnet sind.

24. Vorrichtung nach Anspruch 17, wobei die Sensoren (5) nicht eindringende Sensoren einschließen, die aus piezoelektrischem Material gebildet sind.

25. Vorrichtung nach Anspruch 17, wobei die Sensoren an mindestens einer Stelle eingebaut sind, die aus der aus einem Fahrzeugsitz (13), einer Fahrzeugrücklehne (15), einer Fahrzeugkopfstütze (17), einem Fahrzeuglenkrad (19), einer Fahrerjacke (21), einer Fahrermütze (23), einer Handgelenkbefestigung (25) und einer Halskette (27) bestehenden Gruppe ausgewählt ist.

26. Vorrichtung nach Anspruch 17, wobei der Prozessor (29) in einem Fahrzeug liegt.

27. Vorrichtung nach Anspruch 17, wobei die Sensoren die detektierten Parameter über Funktechnologie (33) zu dem Prozessor übertragen.

28. Vorrichtung nach Anspruch 17, wobei das Warnsignal so gestaltet ist, dass es den Fahrer eines Fahrzeugs vor einem bevorstehenden Schlafzustand alarmiert.

29. Vorrichtung nach Anspruch 17, wobei die Sensoren so ausgeführt sind, dass sie mindestens zwei physiologische Parameter detektieren, die von der aus Herzfrequenz, Atmungsfrequenz, Blutdruck, Temperatur, Herzleistung und Bewegung der Person bestehenden Gruppe ausgewählt sind.

30. Vorrichtung nach Anspruch 17, wobei der Prozessor ferner so ausgeführt ist, dass Aktivieren des Warnsignals das Aktivieren eines festen Warnsignals,

wenn sich mindestens ein Signal in einem festen Bereich befindet, und das Aktivieren eines schwachen Warnsignals, wenn sich mindestens zwei Signale in einem schwachen Bereich befinden, umfasst.

31. Vorrichtung nach Anspruch 17, wobei die Sensoren nicht direkt mit der Haut der Person in Berührung kommen.

32. Verfahren nach Anspruch 1, wobei, wenn sich mindestens ein Signal in einem festen Bereich befindet, das Aktivieren eines Warnsignals erfordert, dass das mindestens eine Signal zum Aktivieren des Warnsignals einen vorher bestimmten Zeitraum lang in dem Bereich bleibt.

33. Verfahren nach Anspruch 1, wobei, wenn sich mindestens zwei Signale in einem schwachen Bereich befinden, das Aktivieren eines Warnsignals erfordert, dass das mindestens eine der Signale zum Aktivieren des Warnsignals einen vorher bestimmten Zeitraum lang in dem Bereich bleibt.

34. Vorrichtung nach Anspruch 17, wobei die Sensoren in weicher Polsterung unterhalb des untersten Bettlakens vom Bett (11) der Person untergebracht sind.

Revendications

1. Procédé pour surveiller la physiologie d'une personne et pour fournir une alarme afin d'avertir d'un état indésirable, comprenant le fait :

de placer au voisinage de la personne une pluralité de capteurs (5) configurés pour détecter des paramètres physiologiques de la personne ;
de détecter un ou plusieurs paramètre(s) physiologique(s) de la personne avec lesdits capteurs (5) ;
de convertir le ou les plusieurs paramètre(s) physiologique(s) détecté(s) en signaux ;
d'affecter une plage ferme supérieure de valeurs de signaux pour chaque paramètre physiologique ;
d'affecter une plage ferme inférieure de valeurs de signaux pour chaque paramètre physiologique ;
d'analyser au moins deux des signaux au cours d'une période pour déterminer dans quelle plage chaque signal est situé ;
le procédé étant **caractérisé en ce qu'**il comprend en outre le fait :

d'affecter une plage souple supérieure de valeurs de signal inférieure à la plage ferme supérieure pour chaque paramètre physiologique, où la plage souple supérieure est sélectionnée pour être un départ vers le bas prédéterminé de la plage ferme supérieure ;
d'affecter une plage souple inférieure de valeurs de signal supérieure à la plage ferme inférieure pour chaque paramètre physiologique, où la plage souple inférieure est sélectionnée pour être un départ vers le haut prédéterminé de la plage ferme inférieure ;
d'activer une alarme lorsqu'au moins un signal se trouve dans une plage ferme, et
d'activer une alarme lorsqu'au moins deux signaux se trouvent dans une plage souple.

2. Procédé de la revendication 1, dans lequel l'activation d'une alarme comporte le fait d'activer une alarme ferme lorsqu'au moins un signal se trouve dans une plage ferme et d'activer une alarme souple lorsqu'au moins deux signaux se trouvent dans une plage souple.

3. Procédé de la revendication 1, dans lequel l'activation d'une alarme comporte le fait d'activer une alarme en utilisant une logique floue pour évaluer l'importance de la pluralité de signaux par rapport aux plages ferme et souple.

4. Procédé de la revendication 1, dans lequel chacun de ladite pluralité de capteurs (5) est configuré pour détecter le même paramètre physiologique de la personne.

5. Procédé de la revendication 1, dans lequel chacun de ladite pluralité de capteurs (5) est configuré pour détecter plusieurs paramètres physiologiques différents de la personne.

6. Procédé de la revendication 1, dans lequel les capteurs (5) sont configurés pour détecter au moins deux paramètres physiologiques sélectionnés dans le groupe constitué de fréquence cardiaque, de rythme respiratoire, de pression artérielle, de température, de mouvement et d'émission de bruit.

7. Procédé de la revendication 1, dans lequel les plages de valeurs de signaux sont affectées par un donneur de soins de santé et peuvent varier de manière sélective.

8. Procédé de la revendication 1, dans lequel la plage souple supérieure est automatiquement sélectionnée pour avoir une limite inférieure qui est un pourcentage prédéterminé de la limite inférieure de la plage ferme supérieure, et la plage souple inférieure est automatiquement sélectionnée pour avoir une limite supérieure qui est un pourcentage prédéterminé de la limite supérieure de la plage ferme inférieure.

9. Procédé de la revendication 1, dans lequel chaque paramètre est affecté à une plage souple différente.

10. Procédé de la revendication 1, dans lequel l'amplitude de la plage souple supérieure diffère de l'amplitude de la plage souple inférieure.

11. Procédé de la revendication 1, comprenant en outre le fait
de communiquer une alarme activée à un fournisseur de soins de santé par l'intermédiaire d'un système d'appel d'infirmier préexistant dans un établissement de soins de santé.

12. Procédé de la revendication 1, comprenant en outre le fait
de sélectionner des signaux dans les plages supérieures qui augmentent en valeur et des signaux dans les plages inférieures qui diminuent en valeur ;
d'activer une alarme lorsqu'au moins l'un desdits signaux sélectionnés se trouve dans une plage ferme ; et
d'activer une alarme lorsqu'au moins deux desdits signaux sélectionnés se trouvent dans une plage souple.

13. Procédé de la revendication 1, comprenant en outre le fait
d'appliquer une fonction de logique floue à chaque signal à l'intérieur d'une plage ; et
d'activer une alarme lorsque la somme des fonctions de logique floue dépasse une valeur prédéterminée.

14. Procédé de la revendication 13, dans lequel une première valeur prédéterminée active une alarme souple.

15. Procédé de la revendication 13, dans lequel une deuxième valeur prédéterminée active une alarme ferme.

16. Procédé de la revendication 1, dans lequel la plage souple supérieure est automatiquement sélectionnée pour avoir une limite inférieure qui est un pourcentage fixe de la limite inférieure de la plage ferme supérieure, et la plage souple inférieure est automatiquement sélectionnée pour avoir une limite supérieure qui est un pourcentage fixe de la limite supérieure de la plage ferme inférieure.

17. Appareil pour surveiller la physiologie d'une personne et pour fournir une alarme afin d'avertir d'un état indésirable, comprenant :

une pluralité de capteurs (5) pour détecter un ou plusieurs paramètre(s) physiologique(s) de la personne ;
un processeur configuré pour convertir chacun du ou des plusieurs paramètre(s) physiologique(s) détecté(s) en signaux d'informations ; et un système d'alarme en communication avec le processeur, le système d'alarme étant configuré pour fournir une ou plusieurs alarme(s) :

dans lequel le processeur est configuré pour effectuer des étapes comportant le fait :

de recevoir une plage ferme supérieure désignée de valeurs de signaux pour chaque paramètre physiologique ;
de recevoir une plage ferme inférieure désignée de valeurs de signaux pour chaque paramètre physiologique ;
d'analyser au moins deux des signaux sur une période pour déterminer dans quelle plage de valeurs chaque signal est situé ;
où l'appareil est **caractérisé en ce que** le processeur est configuré pour effectuer en outre les étapes suivantes qui consistent :

à recevoir une plage souple supérieure désignée de valeurs de signal inférieure à la plage ferme supérieure pour chaque paramètre physiologique ;
à recevoir une plage souple inférieure désignée de valeurs de signal supérieure à la plage ferme inférieure pour chaque paramètre physiologique ;
à activer l'alarme lorsqu'au moins un signal se trouve dans une plage ferme ; et
à activer l'alarme lorsqu'au moins deux signaux se trouvent dans une plage souple.

18. Appareil de la revendication 17, comprenant en outre une interface (9) pour relier le système d'alarme à un système d'appel d'infirmier existant (7) dans un établissement de soins de santé.

19. Appareil de la revendication 17, dans lequel le processeur est logé dans une unité de chevet (3) pour placer à côté d'un lit (11) pour la personne.

20. Appareil de la revendication 19, dans lequel l'unité de chevet comprend en outre un dispositif d'affichage relié au processeur pour afficher des données physiologiques, le dispositif d'affichage étant automatiquement actionné lorsqu'un état d'alarme se produit.

21. Appareil de la revendication 19, dans lequel l'unité de chevet comprend en outre un dispositif d'affichage relié à un processeur pour afficher des données physiologiques, le dispositif d'affichage étant sélectivement activé par un fournisseur de soins de santé assistant.

22. Appareil de la revendication 17, dans lequel les capteurs (5) sont assemblés dans un réseau enfermé dans une couverture.

23. Appareil de la revendication 17, dans lequel les capteurs (5) sont disposés à l'intérieur d'une literie pour la personne.

24. Appareil de la revendication 17, dans lequel les capteurs (5) comprennent des capteurs non invasifs formés d'un matériau piézo-électrique.

25. Appareil de la revendication 17, dans lequel les capteurs sont installés dans au moins un emplacement sélectionné dans le groupe constitué de siège de véhicule (13), de dossier de siège de véhicule (15), d'appui-tête de véhicule (17), de volant de véhicule (19), de veste de conduite (21), de bonnet de conduite (23), d'élément de fixation au poignet (25) et de collier (27).

26. Appareil de la revendication 17, dans lequel le processeur (29) est situé dans un véhicule.

27. Appareil de la revendication 17, dans lequel les capteurs transmettent les paramètres détectés au processeur par l'intermédiaire d'une technologie sans fil (33).

28. Appareil de la revendication 17, dans lequel l'alarme est configurée pour alerter un conducteur d'un véhicule de l'approche d'un état de sommeil.

29. Appareil de la revendication 17, dans lequel les capteurs sont configurés pour détecter au moins deux paramètres physiologiques sélectionnés dans le groupe constitué de fréquence cardiaque, de rythme respiratoire, de pression artérielle, de température, de débit cardiaque et de mouvement de la personne.

30. Appareil de la revendication 17, dans lequel le processeur est en outre configuré de sorte que l'activation de l'alarme comporte le fait d'activer une alarme ferme lorsqu'au moins un signal se trouve dans une plage ferme, et d'activer une alarme souple lorsqu'au moins deux signaux se trouvent dans une plage souple.

31. Appareil de la revendication 17, dans lequel les capteurs ne sont pas directement en contact avec la peau de la personne.

32. Procédé de la revendication 1, dans lequel l'activation d'une alarme lorsqu'au moins un signal se trouve dans une plage ferme nécessite que ledit au moins un signal reste dans ladite plage pendant une période prédéterminée pour activer ladite alarme.

33. Procédé de la revendication 1, dans lequel l'activation d'une alarme lorsqu'au moins deux signaux sont dans une plage souple nécessite que ledit au moins un signal desdits signaux reste dans ladite plage pendant une période prédéterminée pour activer ladite alarme.

34. Appareil de la revendication 17, dans lequel les capteurs sont placés dans un rembourrage souple sous le drap de dessous du lit (11) de la personne.

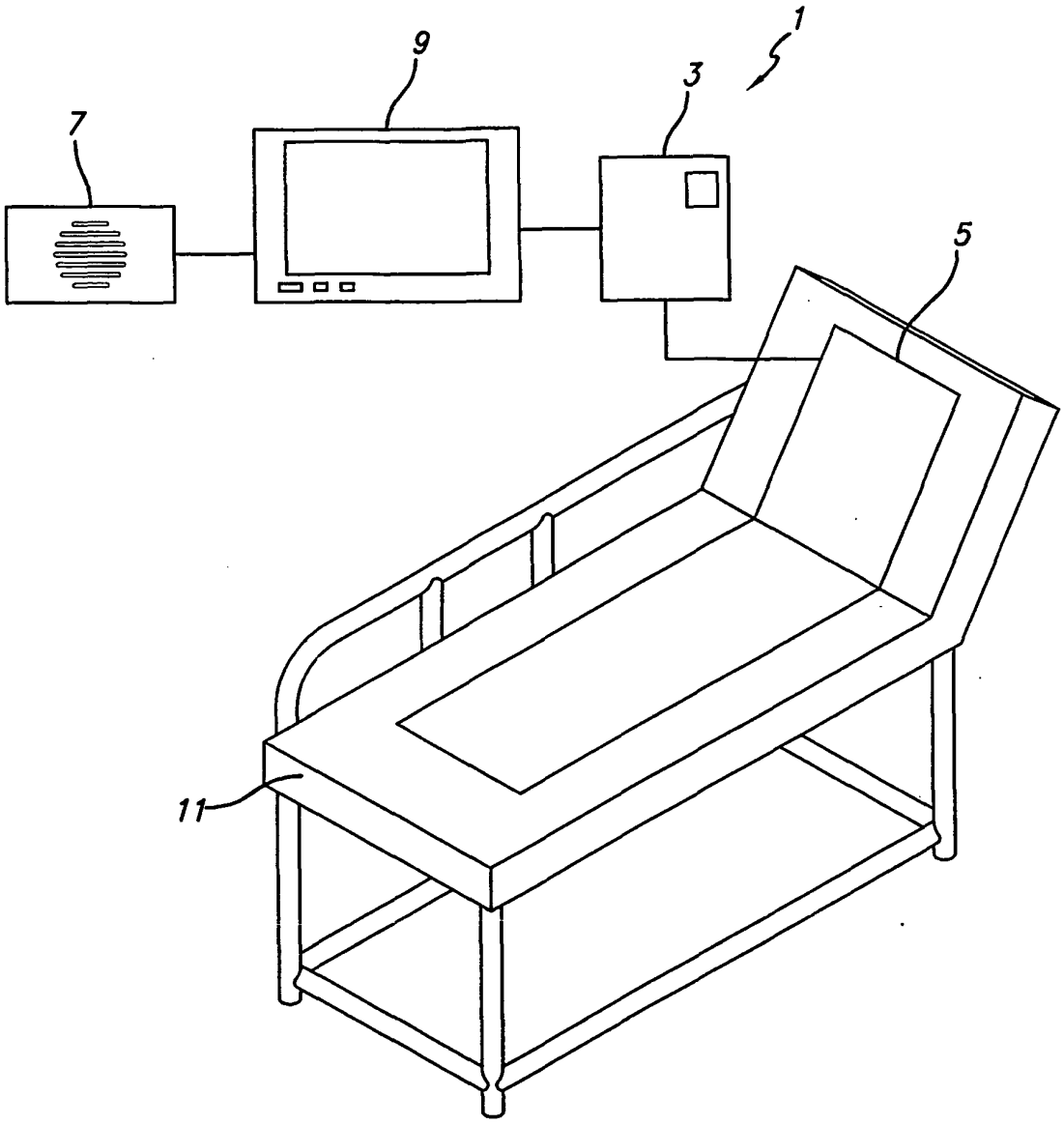

FIG. 1

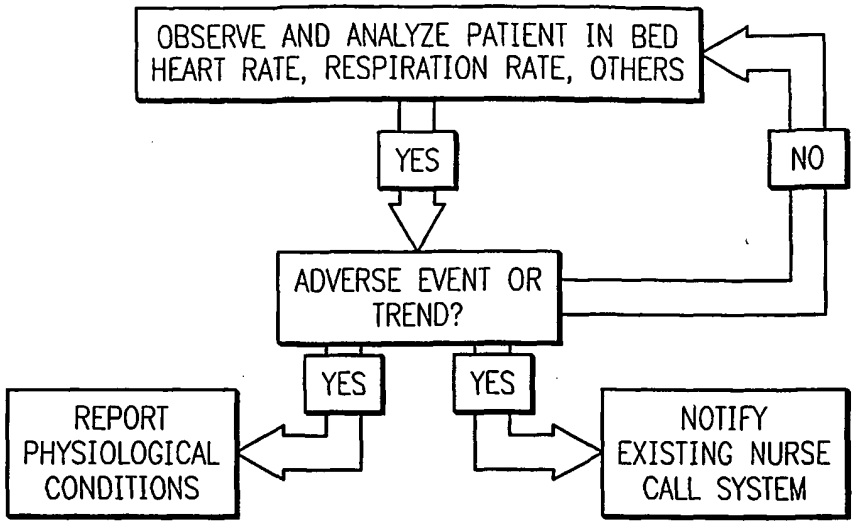
OBSERVE AND ANALYZE PATIENT IN BED
HEART RATE, RESPIRATION RATE, OTHERS
YES
NO
ADVERSE EVENT OR TREND?
YES
YES
REPORT PHYSIOLOGICAL CONDITIONS
NOTIFY EXISTING NURSE CALL SYSTEM

FIG. 2

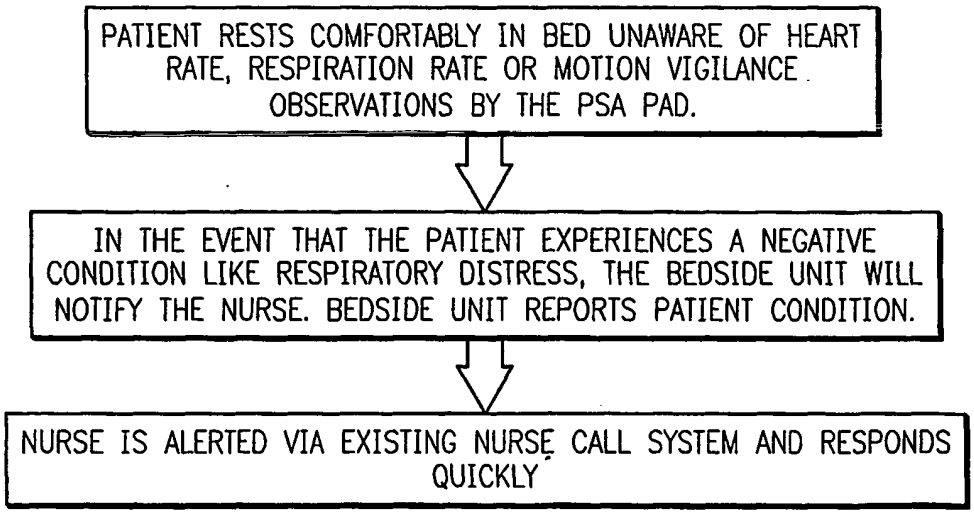
PATIENT RESTS COMFORTABLY IN BED UNAWARE OF HEART RATE, RESPIRATION RATE OR MOTION VIGILANCE. OBSERVATIONS BY THE PSA PAD.
IN THE EVENT THAT THE PATIENT EXPERIENCES A NEGATIVE CONDITION LIKE RESPIRATORY DISTRESS, THE BEDSIDE UNIT WILL NOTIFY THE NURSE. BEDSIDE UNIT REPORTS PATIENT CONDITION.
NURSE IS ALERTED VIA EXISTING NURSE CALL SYSTEM AND RESPONDS QUICKLY

FIG. 3

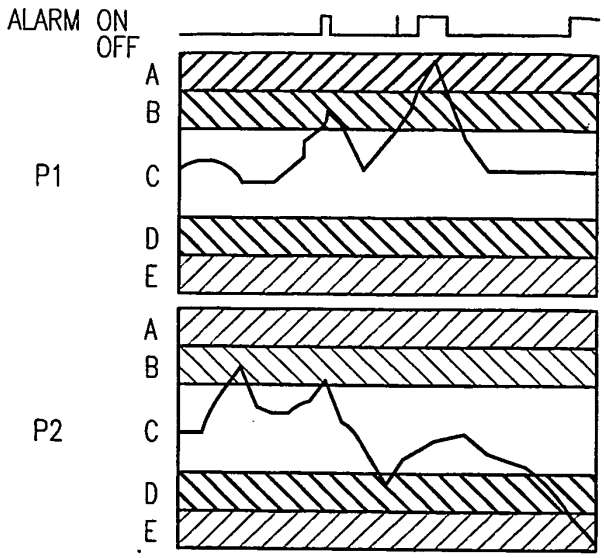

FIG. 4

PARAMETER 1 (P1)	PARAMETER 2 (P2)	ALARM	NOTES
A	A OR B OR C OR D OR E	YES	P1 ⇧ (HARD)
A OR B OR C OR D OR E	A	YES	P2 ⇧ (HARD)
E	A OR B OR C OR D OR E	YES	P1 ⇩ (HARD)
A OR B OR C OR D OR E	E	YES	P2 ⇩ (HARD)
B	B	YES	P1 ⇧ P2 ⇧ (SOFT)
B	C	NO	
B	D	YES	P1 ⇩ P2 ⇩ (SOFT)
C	B	NO	
C	C	NO	
C	D	NO	
D	B	YES	P1 ⇩ P2 ⇧ (SOFT)
D	C	NO	
D	D	YES	P1 ⇩ P2 ⇩ (SOFT)

FIG. 5

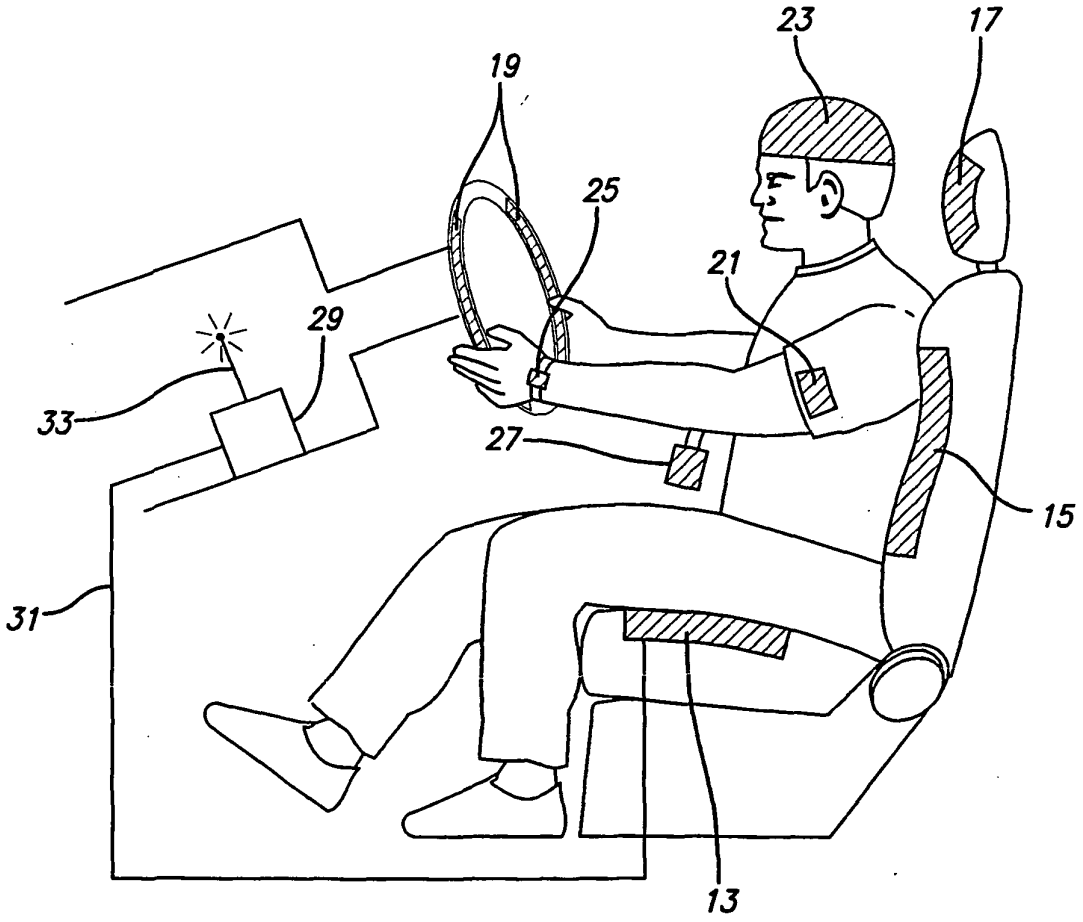

FIG. 6

REFERENCES CITED IN THE DESCRIPTION

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- US 5724025 A, Tavory **[0005]**
- US 5585785 A, Gwin **[0006]**

专利名称(译)	智能医疗警戒系统		
公开(公告)号	EP1694202B1	公开(公告)日	2014-12-31
申请号	EP2004812817	申请日	2004-12-03
申请(专利权)人(译)	HOANA MEDICAL，INC.		
当前申请(专利权)人(译)	HOANA MEDICAL，INC.		
[标]发明人	SULLIVAN PATRICK K GLEI MATTHEW S EMBREE PAUL M		
发明人	SULLIVAN, PATRICK, K. GLEI, MATTHEW, S. EMBREE, PAUL, M.		
IPC分类号	A61B5/00 G08B23/00 G06F19/00 G08B21/04 A61B5/0205 A61B5/0245 A61B5/08 A61B5/18		
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优先权	60/526612 2003-12-04 US		
其他公开文献	EP1694202A4 EP1694202A1		
外部链接	Espacenet		

摘要(译)

一种智能医疗警戒系统，可以观察和分析，并且只有在临床上显着的负面情况下，才能利用医院现有的护士呼叫系统向护理人员报告和报告事件。该装置包括床垫单元，其连接到具有传感器阵列（放置在患者下方）的垫或床罩，并且还通过接口连接到现有的医院护士呼叫系统。在物理床边单元内是信号处理器和报警处理器，其测量数据并评估临床上重要事件是否正在发生。床头单元是一个壁挂式单元，其显示器在启用报警条件时变为活动状态。传感垫或覆盖物是薄的压电薄膜或其他类似的传感技术，其中传感器阵列包覆在柔软的衬垫中并且不直接与患者的皮肤接触。护士呼叫功能由硬件，软件和电缆组成，以连接到已安装在医院或护理机构中的护士呼叫系统。监控系统也可以安装在车辆中以监控操作员的生理状况。