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(54) **STEPPED ALARM METHOD FOR PATIENT MONITORS**

GESTUFTES ALARMVERFAHREN FÜR PATIENTENMONITORE

PROCÉDÉ D'ALARME INCRÉMENTIEL POUR DES MONITEURS DE PATIENT

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(73) Proprietor: **Koninklijke Philips N.V.**
5656 AE Eindhoven (NL)

(72) Inventors:
- **ESHELMAN, Larry, James**
  NL-5656 AE Eindhoven (NL)
- **FEDDES, Bastiaan**
  NL-5656 AE Eindhoven (NL)
- **FLOWER, Abigail, Acton**
  NL-5656 AE Eindhoven (NL)
- **LAMBERT, Nicolaas**
  NL-5656 AE Eindhoven (NL)
- **LEE, Kwok, Pun**
  NL-5656 AE Eindhoven (NL)
- **TJAN, Davy, Hin, Tjiang**
  NL-5656 AE Eindhoven (NL)
- **DE WAELE, Stijn**
  NL-5656 AE Eindhoven (NL)
- **GROSS, Brian, David**
  NL-5656 AE Eindhoven (NL)
- **FRASSICA, Joseph, J.**
  NL-5656 AE Eindhoven (NL)
- **NIELSEN, Larry**
  NL-5656 AE Eindhoven (NL)
- **SAEED, Mohammed**
  NL-5656 AE Eindhoven (NL)
- **CAO, Hanqing**
  NL-5656 AE Eindhoven (NL)

(74) Representative: **Steffen, Thomas**
Philips Intellectual Property & Standards
High Tech Campus 5
5656 AE Eindhoven (NL)

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Description

[0001] The present application relates generally to patient monitoring. It finds particular application in conjunction with reducing patient alarms and will be described with particular reference thereto. However, it is to be understood that it also finds application in other usage scenarios, and is not necessarily limited to the aforementioned application.

[0002] Patient deterioration is often preceded by a period of abnormal vital signs. As such, clinicians often employ predictive systems to assess the likelihood of deterioration. Such systems include abnormality scoring system, such as early warning scores (EWS) and modified EWSs (MEWS) scoring systems. Abnormality scoring systems unify assessments of a plurality of physiological parameters, such as vital signs, into a unified unit system and combine the individual assessments so as to determine a patient risk, which may lead to preventable adverse events like cardiac arrest or death.

[0003] For a sample EWS scoring system (FIGURE 1), a EWS is determined based on several vital signs using a table. When a vital sign is normal, it is assessed a score of zero. With increasing degrees of abnormality of each vital sign, more points are assessed for the vital sign. The total score over all vital signs is an indication of abnormality, and, if it exceeds a preselected threshold, a follow up action is defined (e.g., a consultation by a clinician or activation of a so-called Rapid Response Team).

[0004] Clinicians typically perform abnormality scoring systems manually. However, one challenge with manually scoring is that the resources of medical institutions, such as hospitals, are limited. Therefore, patients in, for example, the general ward are infrequently assessed, typically once per 4-8 hours. Patients can deteriorate unnoticed in this sub-acute care setting. Late discovery of this deterioration can lead to unnecessary complications, intensive care unit (ICU) admission, cardiac arrest, death, and so on.

[0005] To alleviate this, automatic monitoring of patients is becoming increasingly prevalent. However, a principal challenge with automatic monitoring is alarm fatigue. Alarm fatigue is the condition in which clinicians become de-sensitized to clinical alarms because of the high probability that alarms are not of actual clinical significance.

[0006] One approach to reduce the alarm load is to raise alarm thresholds, typically manually. However, other nurses on the same shifts and subsequent shifts may not notice the high threshold and be lulled into a false sense of patient well being. Further, this reduces sensitivity and increases the likelihood of failing to detect patient deterioration. Another approach is to set an inhibition period after an alarm issues, so similar alarms are not issued until a rearming condition is met. In such an approach, the rearming condition is crucial to the reducing alarms.

[0007] The typical rearming condition is the passing of a predetermined inhibition period from the alarm triggering. This is based on the notion that any alarm following the first alarm is likely to be based on similar physiological data, and thus does not provide any additional information to the clinician. The clinician either is already planning to take action to treat the patient if he agrees with the alarm or he doubts the validity of the alarm. In either case, another alarm would be unnecessary. Thus, it is reasonable to inhibit further alarms for a limited period of time.

[0008] One disadvantage of this rearming condition is that additional alarms are not raised if the condition of a patient worsens within the alarm inhibition period. Another disadvantage is the predetermined amount of time is generic to a general patient population. As such, the predetermined amount of time is not tailored to any specific patient. Further, the predetermined amount of time does not adapt to an individual's dynamics.

[0009] Other challenges with automatic monitoring stem from predictive models typically employed by automatic monitoring systems. Such predictive models are typically trained on large databases of population data, whereby decisions using such predictive models are based on the general features of a large population. Further, differences between individuals and the general training population are typically not taken in to account. Training in this way can result in unnecessary alerts and/or failure to generate alerts for certain patients with physiological norms different from those of the general training population.

[0010] One solution is to adjust the predictive models based on knowledge of a patient's healthy, or baseline, physiological dynamics. However, baseline data is often not available in practice, particularly in an ICU, in which it can never be assumed that data being collected reflects the patient's "normal" physiology.

[0011] Another solution employs direct feedback from a clinician about the validity of an issued alarm for learning. However, such an approach is not possible for systems that do not have the benefit of this direct-feedback learning. Further, if alarms are issued in response to predicted events hours in advance, immediate feedback from a clinician about the validity of an alarm is meaningless.

[0012] WO 2011/007271 A1 describes a monitoring system and method in which an alarm is triggered if a monitored parameter exceeds a threshold, which may be constant or vary with time, or if the monitored parameter has not reached a target value by the end of a predefined time period by which an administered drug or therapy should have been effective. The threshold can be varied upon administering any intervention of a therapy for a period of time to limit alarms.

[0013] US 2007/0232880 A1 describes a monitoring system and method in which separate high and low glucose level alarms can be set. These alarms can have different repeat delay periods.

[0014] The present application provides new and improved methods and systems which overcome the above-referenced problems and others.

[0015] In accordance with one aspect, a system for generating patient alarms using a stepped alarm scheme is provided according to claim 1.

[0016] In accordance with another aspect, a method for generating patient alarms using a stepped alarm scheme is provided according to claim 10.

[0017] One advantage resides in increased sensitivity to abnormal patient conditions while reducing alarm loads.

[0018] Another advantage resides in sensitivity to absolute thresholds.

[0019] Another advantage resides in a low alarm load.

[0020] Another advantage resides in sensitivity to patient deterioration.

[0021] Another advantage resides in applicability to a single physiological parameter, as well as a plurality of physiological parameters.

[0022] Another advantage resides in intuitive parameters that are straightforward to tune.

[0023] Another advantage resides in minimizing bedside modification of alarm thresholds.

[0024] Another advantage resides in adjusting to cases in which a patient has conditions that are not typical of the average population.

[0025] Still further advantages of the present invention will be appreciated to those of ordinary skill in the art upon reading and understanding the following detailed description.

[0026] The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating the preferred embodiments and are not to be construed as limiting the invention.

FIGURE 1 is a table illustrative of a EWS scoring system.

FIGURE 2 is a graph illustrative of a method of generating patient alarms using measurements for a vital sign according to aspects of the present disclosure.

FIGURE 3 is a graph illustrative of a method of generating patient alarms using abnormality scores according to aspects of the present disclosure.

FIGURE 4 is a block diagram of a method of generating patient alarms according to aspects of the present disclosure.

FIGURE 5 is a graph illustrating a discrete and piecewise linearized EWS scoring system.

FIGURE 6 is a graph illustrating a signed EWS scoring system (discrete and piecewise linearized).

FIGURE 7 is a graph illustrating a sample relation between alarm threshold and number of alarms per patient per day for different inhibition periods.

FIGURE 8 is a graph illustrating a sample relation between a change in EWS versus alarms per patient per day.

FIGURE 9 is a graph illustrating a sample relation between alarms per patient per day and time between alarms for different ΔEWSs.

FIGURE 10 is graphical depiction illustrating an unstable patient condition.

FIGURE 11 is a graphical illustration of an approach to detecting an unstable patient condition.

FIGURE 12 is a graph illustrating a sample relation between width of an inhibition zone (ε) and number of alarms per patient per day.

FIGURE 13 is a graphical illustration of the unstable patient condition of FIGURE 10 in EWS-space.

FIGURE 14 is a graph illustrating a change in a sample patient's vital signs from being too high to too low.

FIGURE 15 is a graph illustrating the relation between number of alarms per patient per hour and hour of day.

FIGURE 16 is a block diagram of a method of rearming alarm levels according to aspects of the present disclosure.

FIGURE 17 is a graphical illustration of rearming of an alarm level.

FIGURE 18 is a block diagram of an IT infrastructure according to aspects of the present disclosure.

[0027] With reference to FIGURES 2 and 3, illustrative examples of a method 100 (see FIGURE 4) for generating patient alarms using a stepped alarm scheme are provided. Suitably, a patient monitor, such as a wearable patient monitor, a bedside patient monitor, and a central patient monitor, performs the method 100. As discussed in detail hereafter, by using a stepped alarm scheme in combination with long inhibition periods, fewer alarms are produced while still being sensitive to patient deterioration. FIGURE 2 assesses patient deterioration using vital sign measurements for a single vital sign (e.g., respiration rate); whereas FIGURE 3 assesses patient deterioration using an abnormality score (e.g., EWS) that can typically be calculated from a vital sign.

[0028] Vital sign measurements include measurements of vital signs, such as heart rate, temperature, blood oxygen saturation, level of consciousness, pain, urine output, and so on. Abnormality scores, such as EWS and MEWS, combine vital sign measurements for a plurality of vital signs into a score assessing the risk of death of a patient. Abnormality scoring systems provide a non-linear weighting to arrive at an "equally serious" rating scale for each vital sign. In that regard, all of the vital signs going into an abnormality score are assessed using this rating scale and summed to arrive at an abnormality score. Typically, the vital signs are assumed to be independent when calculating an abnormality score. However, some combinations of vital signs are more abnormal than others, whereby an abnormality score can further include scores for combinations of vital signs. To improve the sensitivity of an abnormality score for a vital sign, the vital sign can be weighted more heavily during the determination of the abnormality score. Addi-

tionally or alternatively, to improve the sensitivity, the scoring regions for the vital sign can be refined. It is contemplated that abnormality scoring systems can be tailored to individual patients, medical wards, medical institutions, and so on. In certain embodiments, a clinician tailors the abnormality scoring systems manually through use of user input devices. In other embodiments, the abnormality scoring systems are tailored automatically based on patient information from, for example, a patient information system.

[0029] In both examples of FIGURES 2 and 3, at roughly 12:30, an initial threshold is crossed. In the case of FIGURE 2, the threshold is 28 breathes per minute, and, in the case of FIGURE 3, the threshold is a EWS of 2. By exceeding the initial threshold, an alarm is issued, a long inhibition period, such as 8 hours, is applied for alarms of the same condition, and the threshold is raised. Thereafter, in both examples, at roughly 17:00, a second, higher threshold is crossed (i.e., the situation worsens). In the case of FIGURE 2, the threshold is 30 breathes per minute, and, in the case of FIGURE 3, the threshold is a EWS of 3. By exceeding the second threshold, another alarm is sounded, a long inhibition period, such as 8 hours, is applied for alarms of this new condition, and the threshold is raised.

[0030] With reference to FIGURE 4, a block diagram of the method 100 for generating patient alarms using a stepped alarm scheme is provided. Physiological scores and/or physiological parameter values of one or more patients are received 102. A physiological score is an assessment of a physiological condition of a patient, such as hemodynamic stability or risk of death, based on at least one physiological parameter according to a physiological scoring system. A physiological parameter is a measurable or observable feature of a patient. Examples of physiological scores include abnormality scores, and examples of physiological parameters include vital signs.

[0031] Typically, the physiological scores and/or physiological parameter values are received automatically from sensors associated with the patients via, for example, a wired or wireless communications network. However, in other embodiments, the physiological scores and/or physiological parameter values are received manually from clinicians via, for example, user input devices. Further, the physiological scores and/or physiological parameter values are typically received continuously. However, the physiological scores and/or physiological parameter values can alternatively be received upon the occurrence of an event, such as a timer event (e.g., a periodic timer), a patient event, a manually triggered event (e.g., a clinician pressing a button), and so on. In certain embodiments, the physiological scores are received indirectly from the physiological parameter values. In that regard, the physiological scores are automatically calculated from the physiological parameter values. For example, EWSs are calculated from vital sign measurements as discussed above.

[0032] Abnormality scoring systems typically yield integer values. However, this can result in discrete jumps in abnormality scores, especially in cases when a vital sign is fluctuating around a border value. To alleviate this, abnormality scoring systems can be piecewise linearized. With reference to FIGURE 5, an example of a piecewise linearized EWS scoring system for respiration rate is illustrated. The solid lines indicate a piecewise linearized version of the scoring system, and the dashed lines indicate a discrete version of the scoring system. In certain embodiments, a best fit approach is employed for linearization, although other approaches are contemplated.

[0033] Further, while individual scores attributed to vital signs in abnormality scoring systems are typically unsigned, it is contemplated that signed scores can be employed to distinguish between vital sign measurements for vital signs that are too low and too high. For example, such a distinction can be made by adding a plus ("+") and minus ("-") sign to scores for individual vital signs being too high and too low, respectively. With reference to FIGURE 6, an example of signed abnormality scoring for respiration rate is illustrated. As in FIGURE 5, the solid lines indicate a piecewise linearized version of the scoring system, and the dashed lines indicate a discrete version of the scoring system.

[0034] When calculating a physiological score, the situation can arise in which physiological parameter values for less than all the physiological parameters needed to calculate the physiological score are received. Physiological parameter values can be missing due to faulty measurements and/or observations, or can arise from differences in measurement and/or observation periodicity. For example, heart rate measured every minute and non-invasive blood pressure (NIBP) measured every 30 minutes. One solution to this situation is to store **104** the most recent physiological parameter values for each of the physiological parameters needed to calculate a physiological score in, for example, a memory. In that regard, physiological parameter values are used until a new physiological parameter value for the corresponding physiological parameter is received. Other solutions are to derive missing information from other physiological parameters (e.g., both ECG and SpO_2 can supply heart rate data) or a modeled combination of physiological parameters.

[0035] Referring back to FIGURE 4, the physiological scores and/or physiological parameter values are compared **106** to a plurality of alarm levels. Alarm levels can include one or more of thresholds, ranges, and so on. Typically the alarm levels are determined by clinicians and/or defined by policy of the medical institution employing the method **100**, such as a hospital. However, in certain embodiments, alarm levels can be dynamically generated **108**. It is contemplated that alarm levels can be tailored to individual patients, medical wards, medical institutions, and so on. In certain embodiments, a clinician tailors parameters of the physiological scoring systems, such as thresholds of abnormality scoring systems,

manually through use of a user input device. In other embodiments, the physiological scoring systems are tailored automatically based on patient information from, for example, a patient information system.

[0036] While no particular approach to selecting alarm levels is required, the alarm levels should be selected to minimize alarms while maximizing sensitivity to patient deterioration. With reference to FIGURE 7, an example of the relation between alarm threshold for a EWS scoring system and average number of alarms per patient per day for different inhibition periods is provided. When a high alarm threshold and/or long inhibition period is chosen, the number of alarms is low. In contrast, when a low threshold is chosen, the method **100** becomes more sensitive for detection of abnormal vital signs. However, in combination with a long inhibition period, no alarm will be raised in case of further deterioration within the inhibition period.

[0037] One approach to dynamically generate **108** the alarm levels is through the use of a delta and an initial alarm level. For example, if a threshold of 3 for an abnormality score defines an initial alarm level and the delta is 0.5, an initial alarm will sound at 3.0 and another alarm will sound at 3.5, even when still within an inhibition period of the initial alarm level. After raising the other alarm, a new inhibition period for the 3.5 level is set, and another alarm level at 4 will be the next alarm level to trigger if the patient deteriorates further. The delta can be tailored to individual patients, medical wards, medical institutions, and so on. In certain embodiments, a clinician tailors the delta manually through use of a user input device. In other embodiments, the delta is tailored automatically based on patient medical records from, for example, a patient information system. For more severe patients (e.g., patient's with a higher abnormality score), a lower delta can be chosen to increase sensitivity to deterioration. After the inhibition period, the threshold is lowered.

[0038] With reference to FIGURE 8, a graph showing an example of the relation between delta for a EWS scoring system and number of alarms per patient per day. An important observation is that by implementing a delta, the method **100** is very sensitive to further worsening of patient condition while the average alarm load is minimally adversely influenced. Further, setting a delta too high will seldom trigger a new alarm, while setting it too small could cause bursts of alarms in a short period of time. One approach to assess reasonable values for a delta is by plotting time difference between alarms. Referring to FIGURE 9, an example of such a plot for a EWS scoring system is illustrated. Therein, a large peak at 480 minutes is visible, which is a logical consequence from the chosen inhibition period of 480 minutes (8 hours). If a small value for delta (0.5) is chosen, a large peak at short times between alarms becomes visible, which is caused by quickly succeeding alarms during upward trends in the EWS. Based on visual inspection of generated events at the different settings, a reasonable value for delta is in the order of 1-2.

[0039] Referring back to FIGURE 4, in response to a physiological score and/or physiological parameter value falling within an uninhibited one of the alarm levels **110**, an alarm is generated. An alarm suitably notifies a clinician to check on a patient and, in certain embodiments, the severity of the alarm. Thereafter, a long inhibition period, such as on the order of a few hours, is set **112** for the triggered alarm level. In certain embodiments, the inhibition period suppresses alarms for lower alarm levels as well. To ensure clinicians don't miss alarms, the inhibition period is typically set only after the alarm is acknowledgement by, for example, a clinician. The length of the inhibition period can be variable between alarm levels. In certain embodiments, an inhibition period comparable to the duration of a nurse shift (e.g., 8 hours) is employed. Advantageously, this ensures that no alarm is raised for a patient condition that is unchanged during the shift, while a new nurse in the following shift is renotified about the existing patient condition. In other embodiments, an inhibition period until the next nurse shift is employed. However, this has the drawback that numerous alarms will sound at the beginning of each nurse shift. In other embodiments, shorter inhibition periods for higher abnormality scores or vital sign measurements are employed.

[0040] In response to issuing an alarm **114**, in certain embodiments, a short inhibition period across alarm levels is set. In other words, a short inhibition period suspending all alarms is set after issuing an alarm. Suitably, this short inhibition period is on the order of several minutes, such as 5-10 minutes. Advantageously, this reduces alarm load without significantly, if at all, compromising the well being of patients because the typical response time of a nurse in the general ward is in the order of several minutes.

[0041] Abnormality scores have the advantage of being a value that is easy to communicate. For example, 'patient x has a EWS of 6'. However, a drawback is that it no longer reveals what the contributions of the individual vital signs are. This leads to a risk of not detecting changes in the composition of an abnormality score, particularly in the presence of offsetting improvements of some vital signs and deterioration of others. This is undesirable because a constant abnormality score can incorrectly assess a situation as being stable notwithstanding that vital signs are fluctuating. Therefore, in certain embodiments, the composition of abnormality scores is evaluated **116** for changes in composition and, in response to composition changes **118**, an alarm and inhibition period are triggered, as described above.

[0042] An example of a change in composition of an abnormality score (in this case EWS) derived from heart rate (HR) and respiration rate (RR) is shown in FIGURE 10. Gray areas are periods of invalid data, and the crosses (x) denote alarms would have been raised. The dashed horizontal lines are the borders for the regions that score different numbers of 'EWS points'. The EWS points are indicated in large fontsize. A first alarm is

raised around 23:00 hours due to HR, indicated by a cross in both graphs. Then, the HR improves somewhat, while the respiration rate degrades from being somewhat too high to being very much too high. The result is that the EWS remains the same. However, even so, there is an unstable situation, which justifies a new alarm.

[0043] One approach for evaluating **116** (FIGURE 4) an abnormality score for changes in composition according to this example is explained using Subfigures A-C in FIGURE 11. As will be seen below, the signed abnormality scoring of FIGURE 6 finds particular application herein. Subfigures A-C show the case for a two dimensional abnormality score (i.e., EWS) based on, for example, respiration rate (RR) and heart rate (HR). Diagonal lines indicate constant abnormality scores. Further, a highlighted square region **119** represents the minimum alarm level that is set to generate an alarm (in this example a level of 2 is chosen).

[0044] Referring to Subfigure A, a dot **120** indicates a measurement scoring 0.5 points for the respiration being abnormally low (i.e., -0.5) and 1.7 points for the HR being abnormally high (i.e., +1.7). Thus, the total abnormality score is 2.2. After an alarm is triggered, a higher alarm level is automatically selected, as indicated by a highlighted box **122** in subfigure B. This example assumes a delta of 1.0. A highlighted rectangular region **124** (also referred to as the inhibition zone) in subfigure C indicates additional boundaries that are set to prevent the earlier mentioned problem of changes in composition that may go unnoticed. A score vector **126** of the last alarm (i.e., the alarm of Subfigure A) that was raised forms the axis of the highlighted rectangular region **124**. If a current score vector **128** drifts outside of this region, a new alarm will sound, even when the next absolute alarm level (3.0 in this example) has not been raised. Detection of this drift is done by continuously checking the vector distance ϕ between the current score vector **128** and the score vector **126** of the previous alarm. If this distance is larger than a defined, e.g., user set, level ε, an alarm will sound and the highlighted rectangular region **124** is redefined. This calculation of the distances can be done using standard vector algebra. This algebra remains essentially the same in case this approach is extended to more vital signs.

[0045] With reference to FIGURE 12, an example of the number of alarms as a function of distance ε is shown. The values are for an initial EWS of 3, a delta of 1, and an inhibition period of 480 min. As can be seen, if the distance ε is too high, the method **100** will be insensitive to changes in composition, and, if the distance ε is too low, the number of alarms will increase because the width of the highlighted rectangular region **124** becomes similar to the normal fluctuations in score vector composition. Based on FIGURE 12 and also on visual inspection of some of the generated alarms, a reasonable value for the width of the highlighted rectangular region **124** is in the order of 1-4.

[0046] The example of FIGURE 10 can also be plotted in 'EWS space', as shown in FIGURE 13. The measurements are indicated by the interconnected dots, with the arrows **130** indicating the direction of time. The two alarms of FIGURE 10 are indicated in this figure by circles **132**. The highlighted rectangular region **134** (with a ε of 2) is the inhibition region, similar to the highlighted rectangular region **124** described above. Because of the large change in EWS composition, a new alarm is raised.

[0047] Another example of a change in composition of an abnormality score (in this case EWS) derived from heart rate (HR) and respiration rate (RR) is shown in FIGURE 14. Gray areas are periods of invalid data, and the crosses (x) denote the times an alarm would have been raised. The dashed horizontal lines are the borders for the regions that score different number of 'EWS points'. The EWS points are indicated in large fontsize. A first alarm is raised around 12:15 hours, indicated by a cross, because of an abnormally low respiration rate (scoring 3 EWS points). Around 17:15 hours the absolute EWS is still scoring less than 3 points, but the situation is unstable because the respiration is increasing rapidly. If no technical measures are taken, no alarm is issued because: 1) the previous alarm was less than 8 hours ago; 2) the EWS for respiration is still less than what was scored at 12:15 hours; and 3) the perpendicular distance ϕ to the previous alarm vector is small.

[0048] Schematically, the foregoing situation is depicted in Subfigure D of FIGURE 11. Subfigure D shows the case for a two dimensional abnormality score (i.e., EWS) based on, for example, respiration rate (RR) and heart rate (HR). Diagonal lines indicate constant abnormality scores. Further, a highlighted square region **136** represents the minimum alarm level that is set to generate an alarm (in this example a level of 2 is chosen), and a higher alarm level is indicated by a highlighted box **138**. Even more, a current score vector **140** and a score vector **142** of the previous alarm are shown.

[0049] One approach for evaluating an abnormality score for changes in composition according to this example includes calculating the inner product between the current score vector **140** and the score vector **142** of the previous alarm. For an inner product < 0 (rotation more than 90°) the inhibition period should be turned off so as to allow an alarm to be issued.

[0050] With reference to FIGURE 15, the low alarm load that results from the presented approach is shown. The initial alarm level is 3.0, the delta is 1.0, and the inhibition period is 8 hours. This results in an average alarm rate of approximately 0.02 alarms per patient per hour of the day. For a 25 bed ward this would be similar to about one alarm per 2 hours.

[0051] The discussion heretofore dealt with re-arming alarm levels after a predetermined amount of time elapsed. For example, when a physiological score and/or physiological parameter value falls within an alarm level, an alarm is triggered and an inhibition period of a predetermined length is set inhibiting the same alarm level from triggering more alarms until the inhibition period ends.

However, other approaches to rearming are contemplated. With reference to FIGURE 16, a block diagram of an adaptive method **150** of rearming is provided.

[0052] The adaptive method **150** presupposes familiarity with the typical intervention measures taken by clinicians in response to alarms. For example, typical intervention measures taken in response to an alarm for hemodynamic stability include the administration of fluids, vasopressors, or packed red blood cells. Further, the adaptive method **150** presupposes at least one source of clinical data describing intervention measures taken by clinicians in response to alarms. For example, such a source can be a patient information system which clinicians provide data regarding intervention measures taken via a user input device. Even more, the adaptive method **150** presupposes alarms triggered by physiological scores and/or physiological parameter values reflect a patient's stability with regard to a physiological condition, such as hemodynamic stability or nutritional stability. When the foregoing are available, the adaptive method 150 can be employed for rearming.

[0053] When a physiological score and/or physiological parameter value of a physiological scoring system and/or physiological parameter falls within an uninhibited alarm level, an alarm is triggered and the alarm level is inhibited. In response to inhibiting the alarm level, the adaptive method **150** waits **152** a predetermined amount of time, such as three hours. Typically, the physiological scoring system and/or physiological parameter is predictive, such that alarms generated therefrom are triggered in advance of patient deterioration. The predetermined amount of time typically corresponds to this lead time and typically varies depending on the physiological condition of the physiological score and/or physiological parameter value. After the predetermined amount of time has passed, a determination **154** is made as to whether intervention measures were administered during the predetermined amount of time to address the alarm based on received clinical data. This can be based on actual knowledge that an intervention occurred or knowledge of typical past intervention measures of for the physiological condition of the physiological score and/or physiological parameter value.

[0054] If no intervention measures were administered, the adaptive method **150** waits **156** until a current physiological score and/or physiological parameter value of the physiological scoring system and/or physiological parameter has worsened **156** by a threshold amount compared to the physiological score and/or physiological parameter value at the time of the alarm. The threshold amount can be fixed or variable, such as half of the distance to a previous physiological score and/or physiological parameter value of the physiological scoring system and/or physiological parameter. Once the current physiological score and/or physiological parameter value has worsened, the alarm level is rearmed **158**. By rearming in this way, the lack of intervention by a clinician after a significant time has passed is interpreted as an indication that the patient's condition at the time of the first alarm is acceptable, normal, or stable, for that particular patient. Therefore, even though the current physiological score and/or physiological parameter value is abnormal, or unstable, by population standards, the adaptive method learns that it is normal for this patient.

[0055] If intervention measures were administered, this is recognized as acknowledgement by clinicians and further alarms are unnecessary. The adaptive method **150** waits **160** until at least one rearming condition is met. Rearming conditions include a fixed period of time has passed, the current physiological score and/or physiological parameter value has worsened by a predetermined amount compared to the physiological score and/or physiological parameter value at the time of the alarm, the current physiological score and/or physiological parameter value has worsened by more than half of the distance from a previous physiological score and/or physiological parameter value, such as the physiological score and/or physiological parameter value at the time of the alarm, a physiological score and/or physiological parameter value of the physiological scoring system and/or physiological parameter has fallen below a fixed threshold at least once since the alarm, a physiological score and/or physiological parameter value of the physiological scoring system and/or physiological parameter has fallen below a threshold determined by the current boundaries for the alarm level, and a threshold based on the typical changes for the applied intervention. The rearming conditions can be employed singly or in combination with one another. Once intervention is complete and at least one rearming condition is met, the alarm level is rearmed **158**.

[0056] In some embodiments, the physiological scoring system and/or physiological parameter is a vital signs index (VIX). VIX is a physiological scoring system that typically combines low-latency data, such as current physiological parameter values, and, optionally, high-latency data, such as laboratory test results, and/or static data, such as demographics, into a single value reflective of stability of a physiological condition of a patient, such as the patient's hemodynamic status, pulmonary stability, nutritional stability, and so on. VIX values can be calculated continuously and/or upon the happening of an event, such as a timer event, a user input event, the availability of new data, and so on. Further, in some embodiments, the VIX values are saved for historical analysis.

[0057] A VIX value for stability of a physiological condition is calculated by providing values for predictive variables to a VIX model that generates the VIX value based on the predictive variables. The predictive variables are one or more of vital signs, features extracted from the static data, such as ethnicity, and the like relevant to determining the stability of the physiological condition. The VIX values produced by the models are typically probabilities. For example, a VIX value typically ranges between 0 and 1, where the closer the value is to 1, the more likely the patient is to be unstable. The VIX models

can employ any predictive model methodology, such as logistic regression, multinomial logistic regression, linear regression and support vector machine learning.

[0058] In some embodiments, the VIX models include a logistic regression model for hemodynamic stability with the form of:

$$VIX = \frac{1}{1 + e^{-z}},$$

where

$$z = \gamma + \beta_1 * SBP + \beta_2 * SI + \cdots$$

The model takes in to account SBP and SI, which are highly significant predictive variables in determining hemodynamic stability, returns a VIX between zero and one. The higher the VIX, the less stable the patient. In some embodiments, β_1, the coefficient for SBP, is negative. As SBP gets lower, VIX tends to increase, reflecting that the patient is approaching a less stable state. Further, β_2, the coefficient for SI, is positive. As SI gets higher, VIX also tends to increase, again reflecting a decrease in stability.

[0059] With reference to FIGURE 17, a plot of the VIX for a patient and the corresponding inputs, SBP and HR, over the course of several hours is illustrated. An alert is generated at hour 214.5 as the VIX value of the patient crosses the alert threshold. During the course of the three hours that follows the first alert, no intervention is taken. This is interpreted to mean that the patient's dynamics at the time of the first alert are normal, or acceptable, for that particular patient. Therefore, after three hours have passed, no alert is generated because the patient's VIX is not much higher than it was at the time of the first alert. By the time hour 222.5 is reached, however, VIX has significantly increased and, therefore another alert is issued for the patient. It should be noted that at hour 226, the clinician administered vasopressor indicating that, indeed, the patient experienced a clinically notable incident of hemodynamic instability.

[0060] In some embodiments, the physiological scoring system and/or physiological parameter is a baseline VIX (bVIX). bVIX is a physiological scoring system that indicates how a VIX has been behaving over a past predetermined amount of time, such as three hours. Many methods can be used to estimate the trend in a series of VIX values. Some are more sophisticated than others. In one embodiment, a bVIX value is the maximum VIX value or the 90 percentile VIX value within the past predetermined amount of time.

[0061] In view of the foregoing, by interpreting clinical data regarding intervention measures being implemented by the attending clinician, or lack thereof, in the context of the patient's condition upon the issuing of the first alarm, a method of rearming sensitive to a patient's individual physiological differences is provided. The method can suitably be employed to create a predictive alarm system that can learn and adapt to an individual's dynamics in the absence of direct clinician feedback.

[0062] With reference to FIGURE 18, a block diagram illustrates one embodiment of an information technology (IT) infrastructure **200** of a medical institution, such as a hospital. The IT infrastructure **200** includes one or more bedside or spot-check patient monitoring systems **202**, a patient information system **204**, one or more patient information display systems **206**, and the like, interconnected via a communications network **208**. It is contemplated that the communications network **208** includes one or more of the Internet, a local area network, a wide area network, a wireless network, a wired network, a cellular network, a data bus, and the like.

[0063] The patient monitoring systems **202** receive physiological scores and/or physiological parameter values for patients (not shown) cared for by the medical institution. Typically, the patient monitoring systems **202** receive physiological scores and/or physiological parameter values automatically collected via, for example, one or more sensors **210**, such as electrocardiographic (ECG) electrodes, blood pressure sensors, SpO_2 sensors, pulse sensors, thermometers, respiratory sensors, exhaled gas sensors, noninvasive blood pressure (NBP) sensors, and so on, and/or from other components of the IT infrastructure **200**, such as lab equipment or other patient monitoring systems. However, the patient monitoring systems **202** can receive physiological scores and/or physiological parameter values manually collected from clinicians via, for example, user input devices **212**. In certain embodiments, where the physiological scores and/or physiological parameter values are received from user input devices, a display **214** can be employed to facilitate such user input. The physiological scores and/or physiological parameter values are typically received continuously, but can alternatively be received upon the occurrence of an event, such as a timer event.

[0064] When a patient monitoring system receives physiological scores and/or physiological parameter values, a corresponding deterioration detection module **216** is employed to apply the method **100** for generating patient alarms using a stepped alarm scheme to detect patient deterioration. In certain embodiments, physiological scoring is tailored to patients based on patient information in the patient information system **204**. Insofar as deterioration is detected, the patient monitoring system generates an alarm. In certain embodiments, the alarm is generated as an audio and/or visual warning via, for example, a corresponding display. In other embodiments, notification of patient deterioration is provided to another component of the IT infrastructure **200**, such as one of the patient information display systems **206**. Further, in certain embodiments, the method **150** of FIGURE 16 is employed for rearming as opposed to the passing of a predetermined amount of time.

[0065] To carry out the above noted functionality, the patient monitoring systems **202** suitably include one or more memories **218** and one or more processors **220**. Common examples of patient monitoring systems include patient wearable patient monitors, bed-side patient monitors, spot-check patient monitors and central patient monitors. The memories **218** store executable instructions for performing one or more of the above noted functions of the patient monitoring systems and suitably embody the deterioration detection modules **216**. The processors **220** execute the executable instructions stored on the memories **218** to carry out the functions associated with the patient monitoring systems **202**. Where the patient monitoring systems **202** are operative to communicate over the communications network **208**, the patient monitoring systems **202** further include one or more communications units **222** facilitating communication between the processors **220** and the communications network **208**.

[0066] The patient information system **204**, such as a central record medical database, typically acts as a central repository of patient information including, for example, electronic medical records (EMRs). Additionally or alternatively, the patient information system **204** receives and stores one or more of physiological scores, physiological parameter values and clinical data for the patients in one or more memories **224** thereof. Typically the physiological parameter values and/or physiological scores are received from components of the IT infrastructure **200** via, for example, the communications network **208**, but said measurements can be manually entered via one or more user input devices **212, 226**. As to the latter, a user interface presented via a display **228** can facilitate such manual entry. The patient information system **204** further allows components of the IT infrastructure **200** to access stored data, such as the EMRs and/or physiological parameter values for patients, via the communications network **208**.

[0067] To carry out the above noted functionality, the patient information system **204** suitably includes one or more communications units **230**, the memories **224**, and one or more processors **232**. The communications units **230** facilitate communication between the processors **232** and the communications network **208**. The memories **224** store executable instructions for controlling the processors **232** to perform one or more of the above noted functions of the patient information system **204**. The processors **232** execute the executable instructions stored on the memories **224**.

[0068] The patient information display systems **206** receive physiological scores and/or physiological parameter values for the patients cared for by the medical institution over the communications network **208** from a component of the IT infrastructure **200**. Additionally or alternatively, the patient information display systems **206** receive alarms for the patients cared for by the medical institution. Using the received data, the patient information display systems **206** update associated displays **234** to graphically present the data to clinicians and/or generate alarms. As to the latter, audio and/or visual alarms via, for example, the displays **234** are contemplated. Further, in certain embodiments, user input devices **236** of the patient information display systems **206** are employed to acknowledge alarms to the component of the IT infrastructure **200** generating the alarm.

[0069] To carry out the above noted functionality, the patient information display systems **206** suitably include one or more communications units **238**, one or more memories **240**, and one or more processors **242**. The communications units **238** facilitate communication between the processors **242** and the communications network **208**. The memories **240** store executable instructions for controlling the processors **242** to perform one or more of the above noted functions of the patient information display systems **206**. The processors **242** execute the executable instructions stored on the memories **240**.

[0070] As used herein, a memory includes one or more of a non-transient computer readable medium; a magnetic disk or other magnetic storage medium; an optical disk or other optical storage medium; a random access memory (RAM), read-only memory (ROM), or other electronic memory device or chip or set of operatively interconnected chips; an Internet/Intranet server from which the stored instructions may be retrieved via the Internet/Intranet or a local area network; or so forth. Further, as used herein, a processor includes one or more of a microprocessor, a microcontroller, a graphic processing unit (GPU), an application-specific integrated circuit (ASIC), a field-programmable gate array (FPGA), and the like; a user input device includes one or more of a mouse, a keyboard, a touch screen display, one or more buttons, one or more switches, one or more toggles, and the like; and a display includes one or more of a LCD display, an LED display, a plasma display, a projection display, a touch screen display, and the like.

[0071] The invention has been described with reference to the preferred embodiments. Modifications and alterations may occur to others upon reading and understanding the preceding detailed description. For example, although the methods and systems disclosed herein were made using the general ward population in mind, the alarm escalation can be applied to other healthcare settings as well, such as in ICU, emergency care or home monitoring. It is intended that the invention be constructed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

Claims

1. A system (200) for generating patient alarms using a stepped alarm scheme, said system (202) comprising:

one or more processors (220) programmed to:

receive physiological scores and/or physiological parameter values; compare the physiological scores and/or the physiological parameter values to a plurality of alarm levels;
in response to a physiological score and/or physiological parameter value falling within an uninhibited one of the alarm levels, issue an alarm; and,
set a first inhibition period for the uninhibited alarm level after issuing the alarm, wherein an inhibition period is a set period of a predetermined length inhibiting the same alarm level from triggering more alarms until the inhibition period ends,
characterized in that
the one or more processors (220) are further programmed to:

in response to at least one of a plurality of rearming conditions being met, rearming the uninhibited alarm level, the rearming conditions including:

a first rearming condition, which includes:

a predetermined amount of time passed;
no intervention was administered during the predetermined amount of time; and,
a current physiological score and/or physiological parameter value worsened by a predetermined amount compared to the physiological score and/or physiological parameter value; and,

a second rearming condition, which includes:

the predetermined amount of time passed;
intervention was administered during the predetermined amount of time; and,
a rearming condition is met; and
wherein the physiological score and/or physiological parameter value includes a vital signs index (VIX) value calculated from the physiological parameter values using a predictive model of stability of a physiological condition.

2. The system **(200)** according to claim 1, wherein receiving physiological scores and/or physiological parameter values includes calculating the physiological scores from the physiological values.

3. The system **(200)** according to either one of claims 1 and 2, wherein the physiological scores are calculated using an abnormality scoring system, the abnormality scores based on a plurality of vital sign measurements of the physiological parameter values.

4. The system **(200)** according to any one of claims 1-3, wherein the first inhibition period is set in response to acknowledgement of the alarm.

5. The system **(200)** according to any one of claims 1-4, wherein the processors **(220)** are further programmed to:

generate the plurality of alarm levels from an initial alarm level and a delta, wherein the plurality of alarm levels include the initial alarm level and one or more alarm levels of increasing severity, the alarm levels being spaced from the initial alarm level and other ones of the alarm levels by increments of the delta.

6. The system **(200)** according to any one of claims 1-5, wherein the processors **(220)** are further programmed to:

in response to issuing an alarm, set a second inhibition period across all of the plurality of alarm levels, the second inhibition period being shorter than the first inhibition period.

7. The system **(200)** according to any one of claims 1-6, wherein the processors **(220)** are further programmed to:

evaluate abnormality scores of the physiological scores for a change in composition; and,
in response to the change in the composition of the abnormality scores, issue a second alarm; and,
set an inhibition period for the uninhibited alarm level after issuing the second alarm.

8. The system (200) according to any one of claims 1-7, wherein the physiological score and/ or physiological parameter value includes a baseline vital signs index (VIX) value indicating a trend of a VIX over a past predetermined amount of time.

9. The system (200) according to any one of claims 1-8, further including at least one of:

one or more sensors (210) measuring one or more vital signs of the physiological parameter values;
one or more user input devices (212) receiving values of the physiological parameter values and/or the physiological scores; and,
a communications network (208) exchanging physiological scores and/or physiological parameter values between the system (200) and other components (202, 204, 206) connected to the communications network (208);
wherein the physiological scores and/or the physiological parameter values are received from at least one of the sensors (210), the user input devices (212), and the communications network (208).

10. A method (100) for generating patient alarms using a stepped alarm scheme, the method (100) comprising:

receiving (102) physiological scores and/or physiological parameter values;
comparing (106) the physiological scores and/or the physiological parameter values to a plurality of alarm levels; and,
in response to a physiological score and/or physiological parameter value falling within an uninhibited one of the alarm levels, issuing (110) an alarm; and,
setting **(112)** a first inhibition period for the uninhibited alarm level after issuing the alarm, wherein an inhibition period is a set period of a predetermined length inhibiting the same alarm level from triggering more alarms until the inhibition period ends,
characterized in that
in response to at least one of a plurality of rearming conditions being met, rearming the uninhibited alarm level, the rearming conditions including:

a first rearming condition, which includes:

a predetermined amount of time passed;
determining if no intervention was administered during the predetermined amount of time; and,
a current physiological score and/or physiological parameter value worsened by a predetermined amount compared to the physiological score and/or physiological parameter value; and,

a second rearming condition, which includes:

the predetermined amount of time passed;
determining if intervention was administered during the predetermined amount of time; and,
a rearming condition is met; and

wherein the physiological score and/or physiological parameter value includes a vital signs index (VIX) value calculated from the physiological parameter values using a predictive model of stability of a physiological condition.

11. The method **(100)** according to claim 10, wherein receiving **(102)** physiological scores and/or physiological parameter values includes calculating the physiological scores from the physiological values.

12. The method **(100)** according to claim 10, further including:

evaluating **(116)** abnormality scores of the physiological scores for changes in composition; and,
in response to a change in the composition of the abnormality scores, issuing **(118)** an second alarm; and,
setting **(118)** an inhibition period for the uninhibited one of the alarm levels after issuing the second alarm.

13. The method **(100)** according to any one of claims 10-12, further including:

generating **(108)** the plurality of alarm levels from an initial alarm level and an increments delta, wherein the plurality of alarm levels include the initial alarm level and one or more alarm levels of increasing severity, the alarm levels spaced from the initial alarm level and other ones of the alarm levels by one or more of the increments delta.

14. A non-transitory computer readable medium **(218)** carrying software which controls one or more processors **(220)** to perform the method **(100)** according to any one of claims 10-13.

Patentansprüche

1. System (200) zum Erzeugen von Patientenalarmen unter Verwendung eines abgestuften Alarmschemas, wobei das genannte System (202) Folgendes umfasst:

einen oder mehrere Prozessoren (220), die programmiert sind zum:

Empfangen physiologischer Punktzahlen und/oder physiologischer Parameterwerte;
Vergleichen der physiologischen Punktzahlen und/oder der physiologischen Parameterwerte mit einer Vielzahl von Alarmstufen;
Ausgeben eines Alarms in Reaktion darauf, dass eine physiologische Punktzahl und/oder ein physiologischer Parameterwert innerhalb einer ungehemmten der Alarmstufen liegt; und
Einstellen einer ersten Hemmungsperiode für die ungehemmte Alarmstufe nach dem Ausgeben des Alarms, wobei eine Hemmungsperiode eine eingestellte Periode von einer bestimmten Länge ist, in der die gleiche Alarmstufe daran gehindert wird, weitere Alarme auszulösen, bis die Hemmungsperiode endet,

dadurch gekennzeichnet, dass der eine oder mehrere Prozessoren (220) weiterhin programmiert sind zum:

erneuten Scharfschalten der ungehemmten Alarmstufe in Reaktion darauf, dass mindestens eine von einer Vielzahl von Bedingungen zum erneuten Scharfschalten erfüllt ist, wobei die Bedingungen zum erneuten Scharfschalten Folgendes umfassen:

eine erste Bedingung zum erneuten Scharfschalten, die Folgendes umfasst:

den Ablauf einer vorgegebenen Zeitdauer;
während der vorgegebenen Zeitdauer wurde kein Eingriff verabreicht; und
eine aktuelle physiologische Punktzahl und/oder ein aktueller physiologischer Parameterwert hat sich im Vergleich zu der physiologischen Punktzahl und/oder dem physiologischen Parameterwert um einen vorgegebenen Betrag verschlechtert; und

eine zweite Bedingung zum erneuten Scharfschalten, die Folgendes umfasst:

den Ablauf einer vorgegebenen Zeitdauer;
während der vorgegebenen Zeitdauer wurde ein Eingriff verabreicht; und
es wurde eine Bedingung zum erneuten Scharfschalten erfüllt; und
wobei die physiologische Punktzahl und/oder der physiologische Parameterwert einen Vitalzeichenindex- (VIX) Wert umfassen, der anhand der physiologischen Parameterwerte unter Verwendung eines prädiktiven Modells für die Stabilität eines physiologischen Zustands berechnet wurde.

2. System (200) nach Anspruch 1, wobei das Empfangen physiologischer Punktzahlen und/oder physiologischer Parameterwerte das Berechnen der physiologischen Punktzahlen anhand der physiologischen Werte umfasst.

3. System (200) nach einem der Ansprüche 1 und 2, wobei die physiologischen Punktzahlen unter Verwendung eines Abnormalität-Punktzahlsystems berechnet werden, wobei die Abnormalität-Punktzahlen auf einer Vielzahl von Vitalzeichenmessungen der physiologischen Parameterwerte basieren.

4. System (200) nach einem der Ansprüche 1 bis 3, wobei die erste Hemmungsperiode in Reaktion auf eine Bestätigung des Alarms eingestellt wird.

5. System (200) nach einem der Ansprüche 1 bis 4, wobei die Prozessoren (220) weiterhin programmiert sind zum:

Erzeugen der Vielzahl von Alarmstufen ausgehend von einer anfänglichen Alarmstufe und einem Delta, wobei die Vielzahl von Alarmstufen die anfängliche Alarmstufe und eine oder mehrere Alarmstufen von zunehmendem Schweregrad umfasst, wobei die Alarmstufen von der anfänglichen Alarmstufe und anderen der Alarmstufen durch Inkremente des Delta beabstandet sind.

6. System (200) nach einem der Ansprüche 1 bis 5, wobei die Prozessoren (220) weiterhin programmiert sind zum:

Einstellen einer zweiten Hemmungsperiode über alle von der Vielzahl von Alarmstufen in Reaktion auf das Ausgeben eines Alarms, wobei die zweite Hemmungsperiode kürzer ist als die erste Hemmungsperiode.

7. System (200) nach einem der Ansprüche 1 bis 6, wobei die Prozessoren (220) weiterhin programmiert sind zum:

Evaluieren von Abnormalität-Punktzahlen der physiologischen Punktzahlen auf eine Änderung in der Zusammensetzung; und

Ausgeben eines zweiten Alarms in Reakti-

on auf die Änderung in der Zusammensetzung der Abnormalität-Punktzahlen; und
Einstellen einer Hemmungsperiode für die ungehemmte Alarmstufe nach dem Ausgeben des zweiten Alarms.

8. System (200) nach einem der Ansprüche 1 bis 7, wobei die physiologische Punktzahl und/oder der physiologische Parameterwert einen Basis-Vitalzeichenindex- (VIX) Wert umfasst, der einen Trend eines VIX über eine vergangene vorgegebene Zeitdauer angibt.

9. System (200) nach einem der Ansprüche 1 bis 8, das weiterhin mindestens eines von Folgendem umfasst:

einen oder mehrere Sensoren (210), die ein oder mehrere Vitalzeichen der physiologischen Parameterwerte messen;
eine oder mehrere Benutzereingabevorrichtungen (212), die Werte der physiologischen Parameterwerte und/oder der physiologischen Punktzahlen empfangen; und
ein Kommunikationsnetzwerk (208) zum Austauschen physiologischer Punktzahlen und/oder physiologischer Parameterwerte zwischen dem System (200) und anderen Komponenten (202, 204, 206), die mit dem Kommunikationsnetzwerk (208) verbunden sind;
wobei die physiologischen Punktzahlen und/oder die physiologischen Parameterwerte von mindestens entweder den Sensoren (210), den Benutzereingabevorrichtungen (212) oder dem Kommunikationsnetzwerk (208) empfangen werden.

10. Verfahren (100) zum Erzeugen von Patientenalarmen unter Verwendung eines abgestuften Alarmschemas, wobei das Verfahren (100) Folgendes umfasst:

Empfangen (102) physiologischer Punktzahlen und/oder physiologischer Parameterwerte;
Vergleichen (106) der physiologischen Punktzahlen und/oder der physiologischen Parameterwerte mit einer Vielzahl von Alarmstufen; und
Ausgeben (110) eines Alarms in Reaktion darauf, dass eine physiologische Punktzahl und/oder ein physiologischer Parameterwert innerhalb einer ungehemmten der Alarmstufen liegt; und
Einstellen (112) einer ersten Hemmungsperiode für die ungehemmte Alarmstufe nach dem Ausgeben des Alarms, wobei eine Hemmungsperiode eine eingestellte Periode von einer bestimmten Länge ist, in der die gleiche Alarmstufe daran gehindert wird, weitere Alarme auszulösen, bis die Hemmungsperiode endet,

gekennzeichnet durch:

erneuten Scharfschalten der ungehemmten Alarmstufe in Reaktion darauf, dass mindestens eine von einer Vielzahl von Bedingungen zum erneuten Scharfschalten erfüllt ist, wobei die Bedingungen zum erneuten Scharfschalten Folgendes umfassen:

eine erste Bedingung zum erneuten Scharfschalten, die Folgendes umfasst:

den Ablauf einer vorgegebenen Zeitdauer;
Ermitteln, ob während der vorgegebenen Zeitdauer kein Eingriff verabreicht wurde; und
sich eine aktuelle physiologische Punktzahl und/oder ein aktueller physiologischer Parameterwert im Vergleich zu der physiologischen Punktzahl und/oder dem physiologischen Parameterwert um einen vorgegebenen Betrag verschlechtert hat; und

eine zweite Bedingung zum erneuten Scharfschalten, die Folgendes umfasst:

den Ablauf einer vorgegebenen Zeitdauer;
Ermitteln, ob während der vorgegebenen Zeitdauer ein Eingriff verabreicht wurde; und
eine Bedingung zum erneuten Scharfschalten erfüllt ist; und
wobei die physiologische Punktzahl und/oder der physiologische Parameterwert einen Vitalzeichenindex- (VIX) Wert umfassen, der anhand der physiologischen Parameterwerte unter Verwendung eines prädiktiven Modells für die Stabilität eines physiologischen Zustands berechnet wurde.

11. Verfahren (100) nach Anspruch 10, wobei das Empfangen (102) physiologischer Punktzahlen und/oder physiologischer Parameterwerte das Berechnen der physiologischen Punktzahlen anhand der physiologischen Werte umfasst.

12. Verfahren (100) nach Anspruch 10, das weiterhin Folgendes umfasst:

Evaluieren (116) von Abnormalität-Punktzahlen der physiologischen Punktzahlen auf Änderungen in der Zusammensetzung; und

Ausgeben (118) eines zweiten Alarms in Reaktion auf die Änderung in der Zusammensetzung der Abnormalität-Punktzahlen; und
Einstellen (118) einer Hemmungsperiode für die ungehemmte Alarmstufe nach dem Ausgeben des zweiten Alarms.

13. Verfahren (100) nach einem der Ansprüche 10 bis 12, das weiterhin Folgendes umfasst:

Erzeugen (108) der Vielzahl von Alarmstufen ausgehend von einer anfänglichen Alarmstufe und einem Inkremente-Delta, wobei die Vielzahl von Alarmstufen die anfängliche Alarmstufe und eine oder mehrere Alarmstufen von zunehmendem Schweregrad umfasst, wobei die Alarmstufen von der anfänglichen Alarmstufe und anderen der Alarmstufen durch ein oder mehrere Inkremente-Delta beabstandet sind.

14. Nicht-flüchtiges computerlesbares Medium (218) mit Software, die einen oder mehrere Prozessoren (220) steuert, um das Verfahren (100) nach einem der Ansprüche 10 bis 13 durchzuführen.

Revendications

1. Système (200) permettant de générer des alarmes de patients en utilisant un procédé d'alarme échelonné, ledit système (202) comprenant :

un ou plusieurs processeurs (220) programmés pour :

recevoir des scores physiologiques et/ou des valeurs de paramètres physiologiques ;
comparer les scores physiologiques et/ou les valeurs de paramètres physiologiques à une pluralité de niveaux d'alarme ;
en réponse à un score physiologique et/ou à une valeur de paramètre physiologique s'inscrivant dans un non inhibé des niveaux d'alarme, émettre une alarme ; et,
définir une première période d'inhibition pour le niveau d'alarme non inhibé après l'émission de l'alarme, dans lequel une période d'inhibition est une période définie d'une longueur prédéterminée inhibant le déclenchement de plus d'alarmes par le même niveau d'alarme jusqu'à ce que la période d'inhibition se termine,

caractérisé en ce que
l'un ou plusieurs processeurs (220) sont en outre programmés pour :

en réponse à au moins une d'une pluralité de conditions de réarmement remplies, réarmer le niveau d'alarme non inhibé, les conditions de réarmement comprenant :

une première condition de réarmement, qui comprend :

un laps de temps prédéterminé écoulé ;
aucune intervention n'a été administrée pendant le laps de temps prédéterminé ; et,
un score physiologique et/ou une valeur de paramètre physiologique courants aggravés d'une quantité prédéterminée par rapport au score physiologique et/ou à la valeur de paramètre physiologique ; et,

une seconde condition de réarmement qui comprend :

le laps de temps prédéterminé écoulé ;
une intervention a été administrée pendant le laps de temps prédéterminé ; et,
une condition de réarmement est remplie ; et
dans lequel le score physiologique et/ou la valeur de paramètre physiologique comprennent une valeur d'indice de signes vitaux (VIX) calculée à partir des valeurs de paramètres physiologiques en utilisant un modèle prédictif de stabilité d'un état physiologique.

2. Système (200) selon la revendication 1, dans lequel la réception de scores physiologiques et/ou de valeurs de paramètres physiologiques comprend le calcul des scores physiologiques à partir des valeurs physiologiques.

3. Système (200) selon l'une quelconque des revendications 1 et 2, dans lequel les scores physiologiques sont calculés en utilisant un système de calcul de scores d'anomalie, les scores d'anomalie étant basés sur une pluralité de mesures de signes vitaux des valeurs de paramètres physiologiques.

4. Système (200) selon l'une quelconque des revendications 1-3, dans lequel la première période d'inhibition est définie en réponse à un accusé de réception de l'alarme.

5. Système (200) selon l'une quelconque des revendications 1-4, dans lequel les processeurs (220) sont

en outre programmés pour :

générer la pluralité de niveaux d'alarme à partir d'un niveau d'alarme initial et d'un delta, dans lequel la pluralité de niveaux d'alarme comprennent le niveau d'alarme initial et un ou plusieurs niveaux d'alarme de gravité croissante, les niveaux d'alarme étant espacés du niveau d'alarme initial et d'autres des niveaux d'alarme par des incréments du delta.

6. Système (200) selon l'une quelconque des revendications 1-5, dans lequel les processeurs (220) sont en outre programmés pour :

en réponse à l'émission d'une alarme, définir une seconde période d'inhibition à travers toute la pluralité de niveaux d'alarme, la seconde période d'inhibition étant plus courte que la première période d'inhibition.

7. Système (200) selon l'une quelconque des revendications 1-6, dans lequel les processeurs (220) sont en outre programmés pour :

évaluer les scores d'anomalie des scores physiologiques pour un changement de composition ; et,
en réponse au changement de la composition des scores d'anomalie, émettre une seconde alarme ; et,
définir une période d'inhibition pour le niveau d'alarme non inhibé après l'émission de la seconde alarme.

8. Système (200) selon l'une quelconque des revendications 1-7, dans lequel le score physiologique et/ou la valeur de paramètre physiologique comprennent une valeur d'indice de signes vitaux (VIX) de base indiquant une tendance d'un VIX au cours d'un laps de temps prédéterminé passé.

9. Système (200) selon l'une quelconque des revendications 1-8, comprenant en outre au moins un de :

un ou plusieurs capteurs (210) mesurant un ou plusieurs signes vitaux des valeurs de paramètres physiologiques ;
un ou plusieurs dispositifs d'entrée d'utilisateur (212) recevant des valeurs des valeurs de paramètres physiologiques et/ou des scores physiologiques ; et,
un réseau de communications (208) échangeant des scores physiologiques et/ou des valeurs de paramètres physiologiques entre le système (200) et d'autres composants (202, 204, 206) connectés au réseau de communications (208) ;
dans lequel les scores physiologiques et/ou les valeurs de paramètres physiologiques sont reçus depuis au moins un des capteurs (210), des dispositifs d'entrée d'utilisateur (212) et du réseau de communications (208).

10. Procédé (100) permettant de générer des alarmes de patients en utilisant un procédé d'alarme échelonné, le procédé (100) comprenant :

la réception (102) de scores physiologiques et/ou de valeurs de paramètres physiologiques ;
la comparaison (106) des scores physiologiques et/ou des valeurs de paramètres physiologiques à une pluralité de niveaux d'alarme ; et,
en réponse à un score physiologique et/ou à une valeur de paramètre physiologique s'inscrivant dans un non inhibé des niveaux d'alarme, l'émission (110) d'une alarme ; et,
la définition (112) d'une première période d'inhibition pour le niveau d'alarme non inhibé après l'émission de l'alarme, dans lequel une période d'inhibition est une période définie d'une longueur prédéterminée inhibant le déclenchement de plus d'alarmes par le même niveau d'alarme jusqu'à ce que la période d'inhibition se termine,

caractérisé en ce que

en réponse à au moins une d'une pluralité de conditions de réarmement remplies, le réarmement du niveau d'alarme non inhibé, les conditions de réarmement comprenant :

une première condition de réarmement, qui comprend :

un laps de temps prédéterminé écoulé ;
la détermination de si aucune intervention n'a été administrée pendant le laps de temps prédéterminé ; et,
un score physiologique et/ou une valeur de paramètre physiologique courants aggravés d'une quantité prédéterminée par rapport au score physiologique et/ou à la valeur de paramètre physiologique ; et,

une seconde condition de réarmement, qui comprend :

le laps de temps prédéterminé écoulé ;
la détermination de si une intervention a été administrée pendant le laps de temps prédéterminé ; et,
une condition de réarmement est remplie ; et
dans lequel le score physiologique

et/ou la valeur de paramètre physiologique comprennent une valeur d'indice de signes vitaux (VIX) calculée à partir des valeurs de paramètres physiologiques en utilisant un modèle prédictif de stabilité d'un état physiologique.

11. Procédé (100) selon la revendication 10, dans lequel la réception (102) de scores physiologiques et/ou de valeurs de paramètres physiologiques comprend le calcul des scores physiologiques à partir des valeurs physiologiques.

12. Procédé (100) selon la revendication 10, comprenant en outre :

l'évaluation (116) de scores d'anomalie des scores physiologiques pour des changements de composition ; et,
en réponse à un changement de la composition des scores d'anomalie, l'émission (118) d'une seconde alarme ; et,
la définition (118) d'une période d'inhibition pour celui non inhibé des niveaux d'alarme après l'émission de la seconde alarme.

13. Procédé (100) selon l'une quelconque des revendications 10-12, comprenant en outre :

la génération (108) de la pluralité de niveaux d'alarme à partir d'un niveau d'alarme initial et d'un delta d'incréments, dans lequel la pluralité de niveaux d'alarme comprennent le niveau d'alarme initial et un ou plusieurs niveaux d'alarme de gravité croissante, les niveaux d'alarme étant espacés du niveau d'alarme initial et d'autres des niveaux d'alarme par un ou plusieurs du delta d'incréments.

14. Support non transitoire lisible par ordinateur (218) contenant un logiciel qui commande un ou plusieurs processeurs (220) pour mettre en oeuvre le procédé (100) selon l'une quelconque des revendications 10-13.

Score	3	2	1	0	1	2	3
Resp. Rate (/min)		<8		9-14	15-20	21-29	>30
Pulse (/min)		<40	41-50	51-100	101-110	111-130	>130
Temp. (°C)		<35		35-38.4	>38.5		
CNS				Alert	Voice	Pain	Unresp.
Urine (ml/hr)	0	<30	<60		>150		
Sys. BP (mmHg)	<70	<40	71-80	101-199		>200	

FIG. 1 (PRIOR ART)

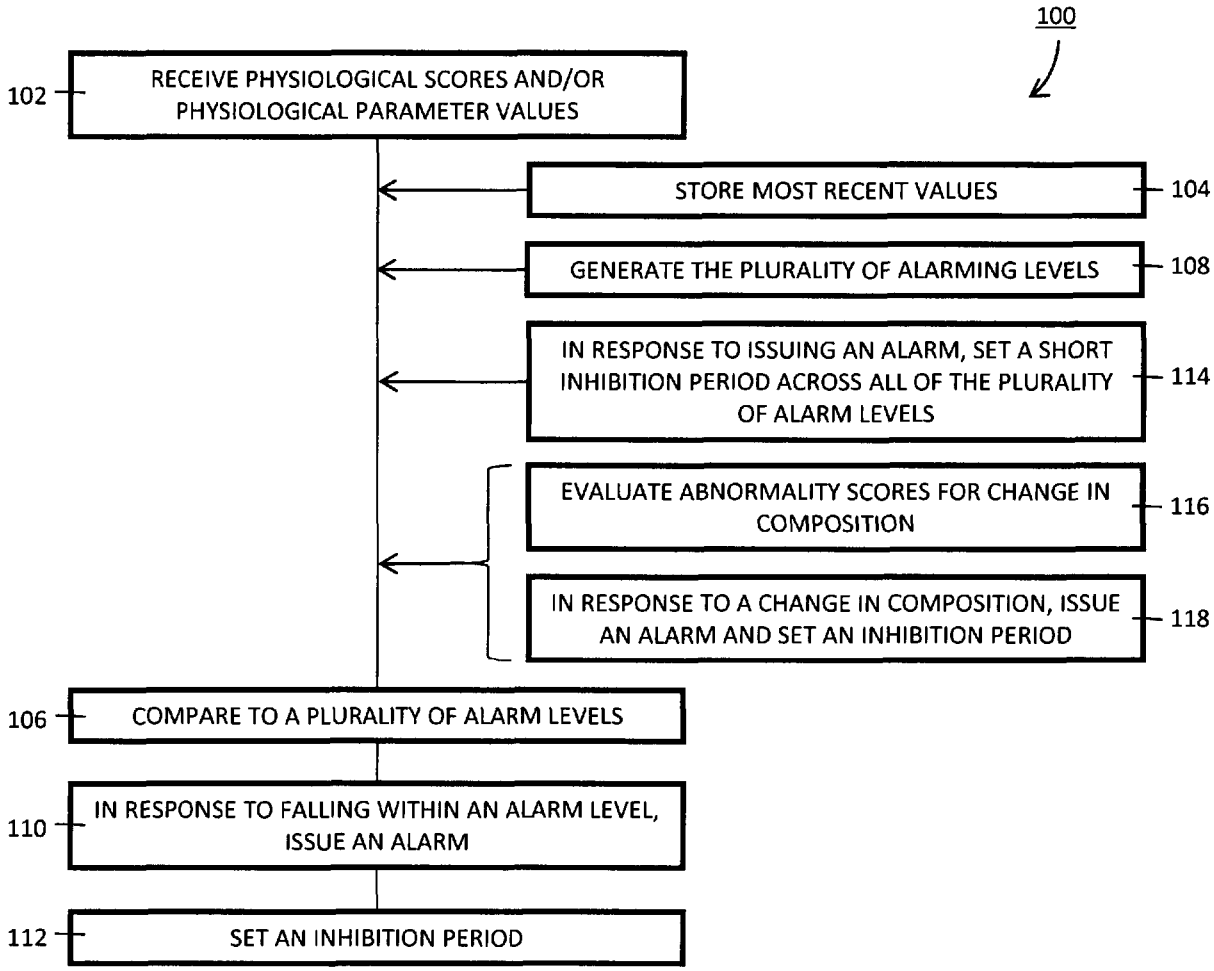

FIG. 4

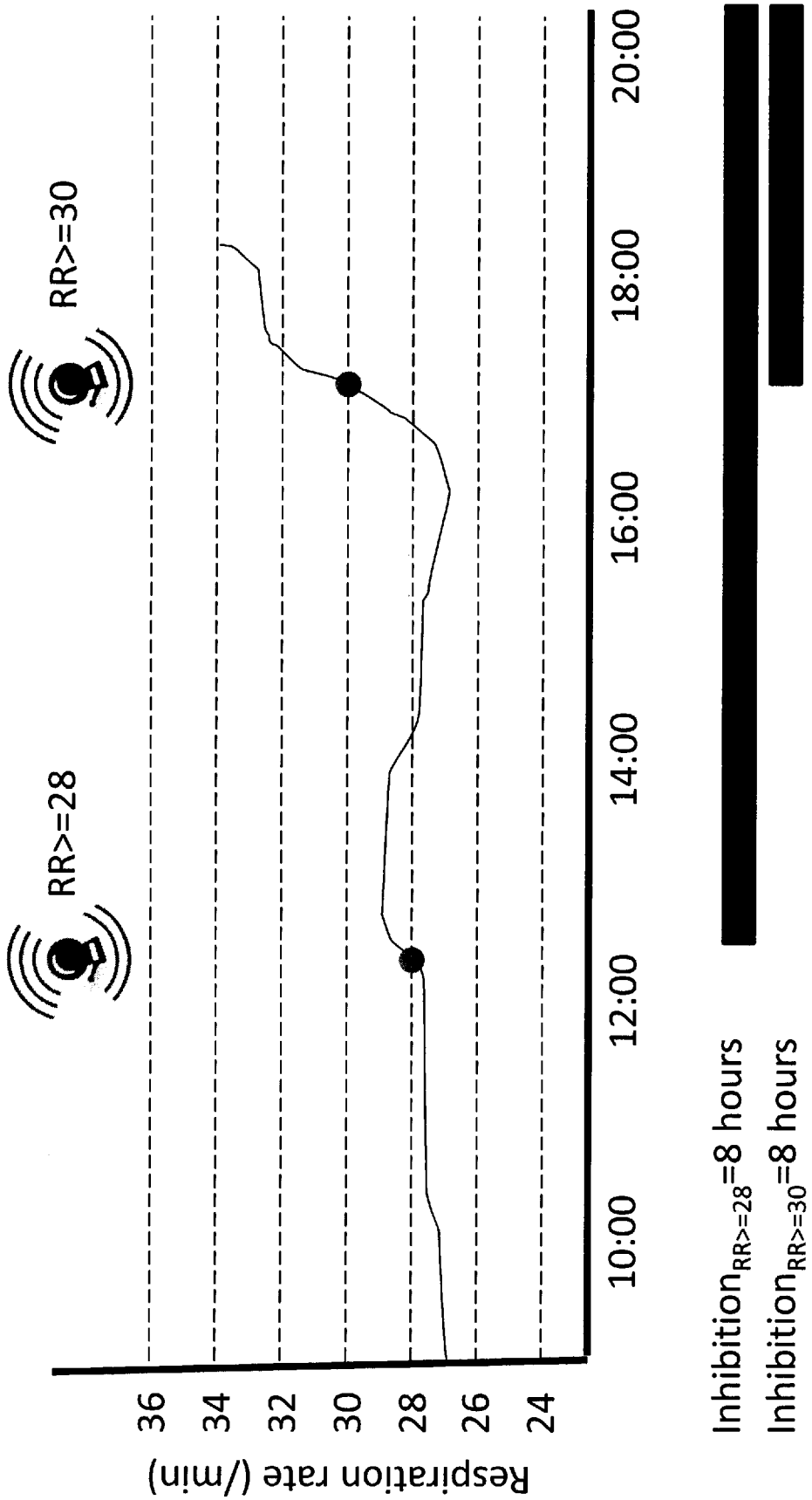
RR>=28
RR>=30
36
34
32
30
28
26
24
Respiration rate (/min)
10:00
12:00
14:00
16:00
18:00
20:00
Inhibition$_{RR>=28}$=8 hours
Inhibition$_{RR>=30}$=8 hours

FIG. 2

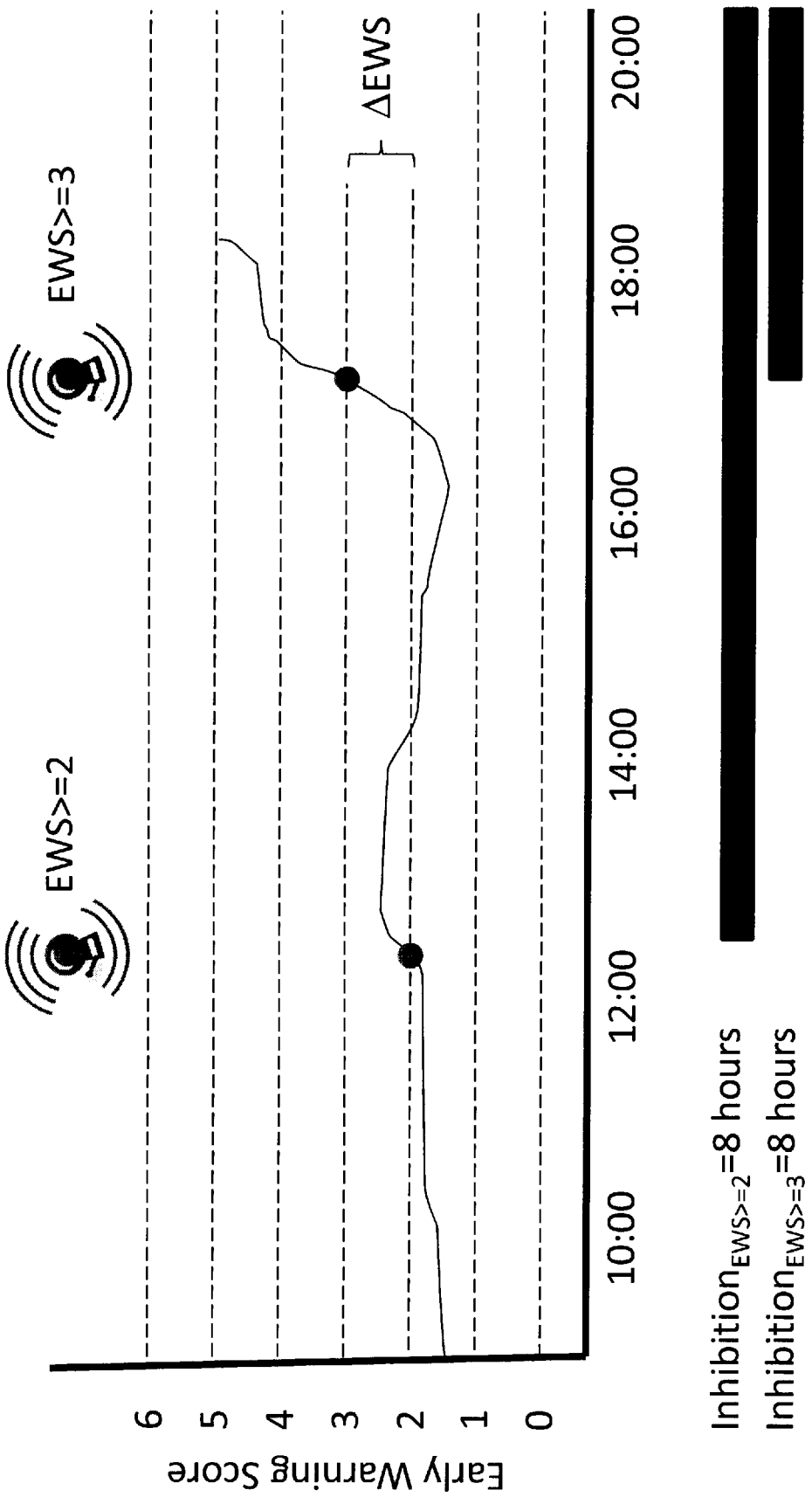
Early Warning Score
6
5
4
3
2
1
0
10:00
12:00
14:00
16:00
18:00
20:00
EWS>=2
EWS>=3
ΔEWS
Inhibition$_{EWS>=2}$=8 hours
Inhibition$_{EWS>=3}$=8 hours

FIG. 3

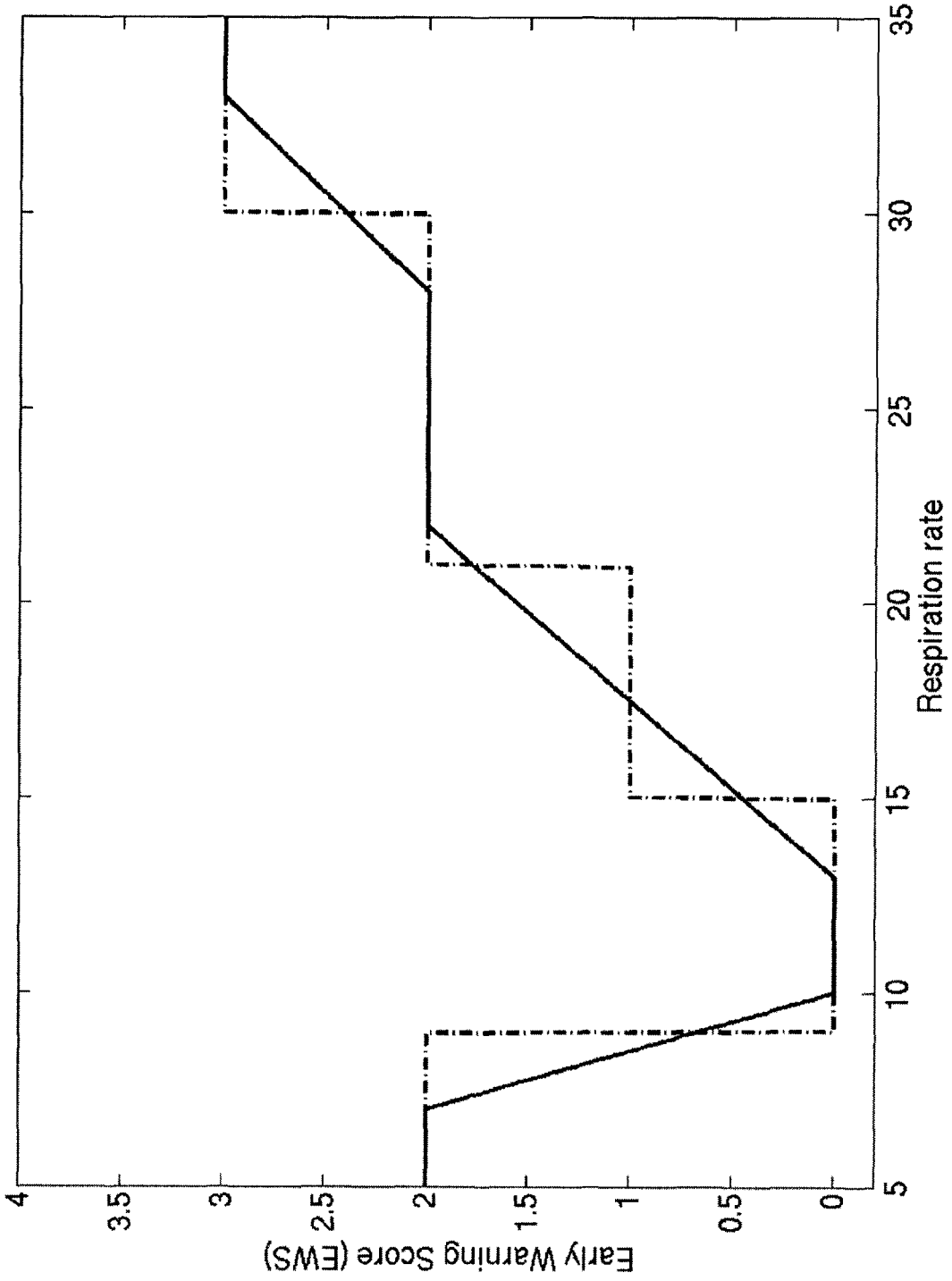
Early Warning Score (EWS)
0
0.5
1
1.5
2
2.5
3
3.5
4
5
10
15
20
25
30
35
Respiration rate

FIG. 5

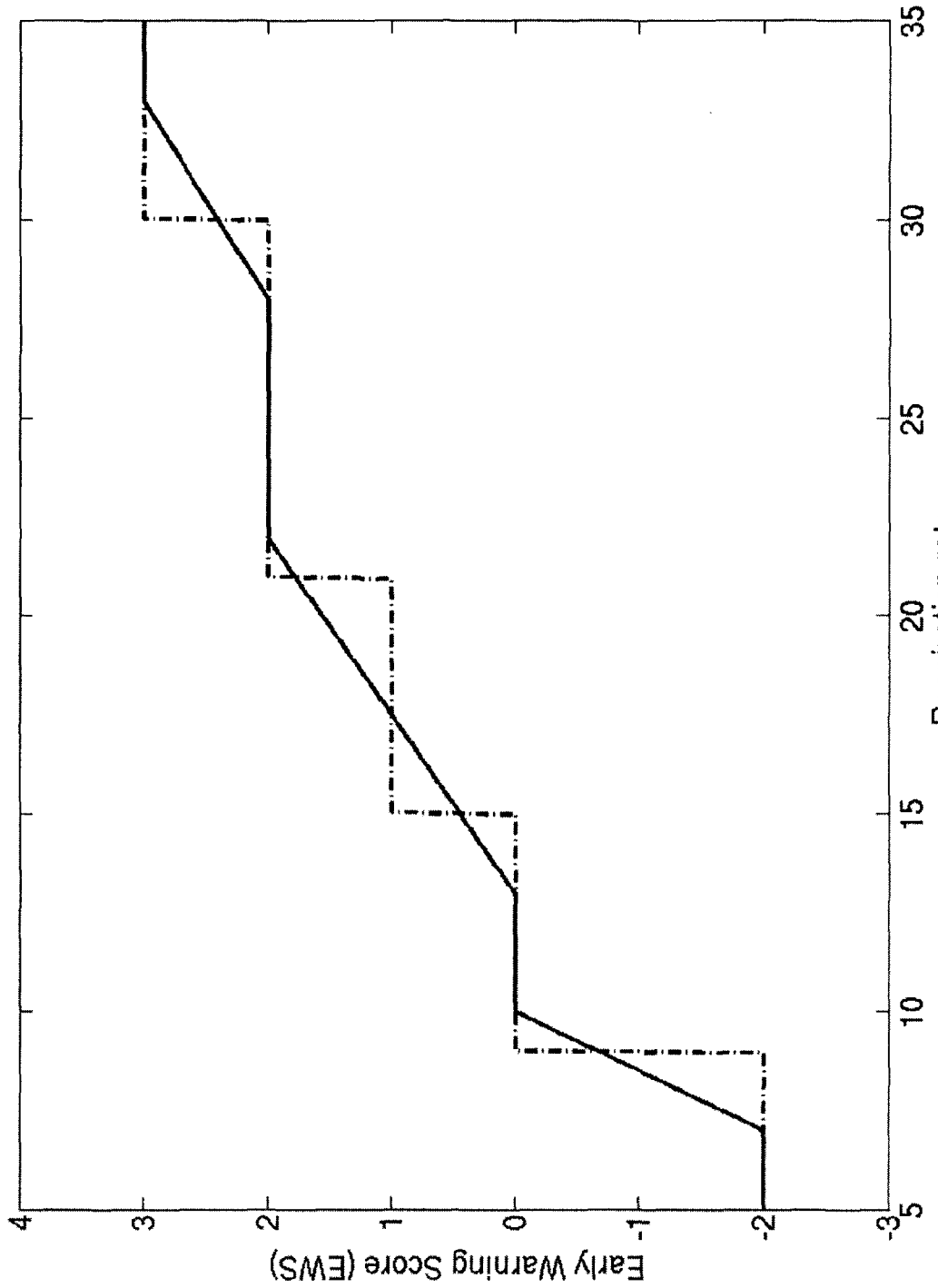
Early Warning Score (EWS)
4
3
2
1
0
-1
-2
-3
5
10
15
20
25
30
35
Respiration rate

FIG. 6

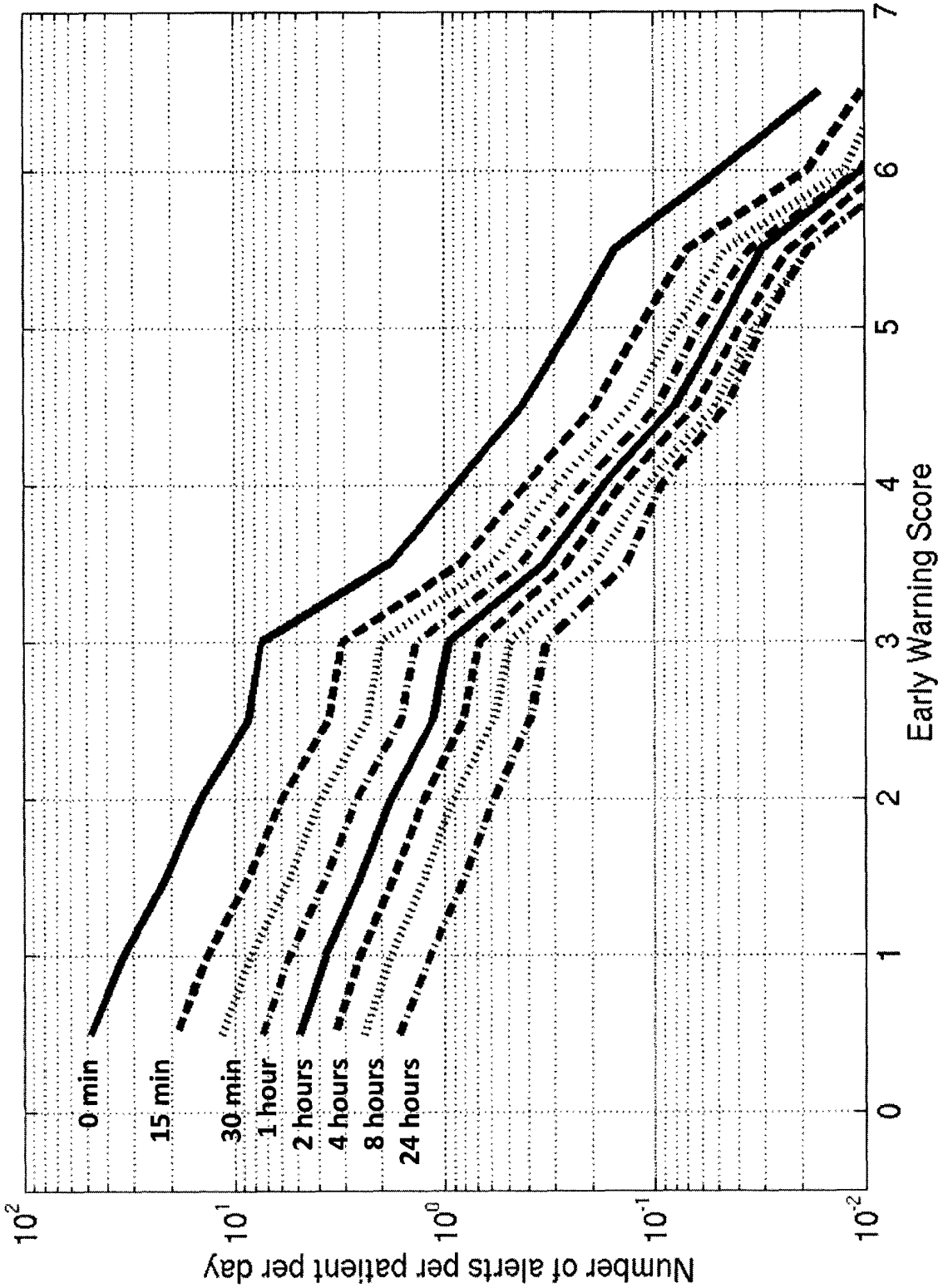
Number of alerts per patient per day
10^{2}
10^{1}
10^{0}
10^{-1}
10^{-2}
0 min
15 min
30 min
1 hour
2 hours
4 hours
8 hours
24 hours
0
1
2
3
4
5
6
7
Early Warning Score

FIG. 7

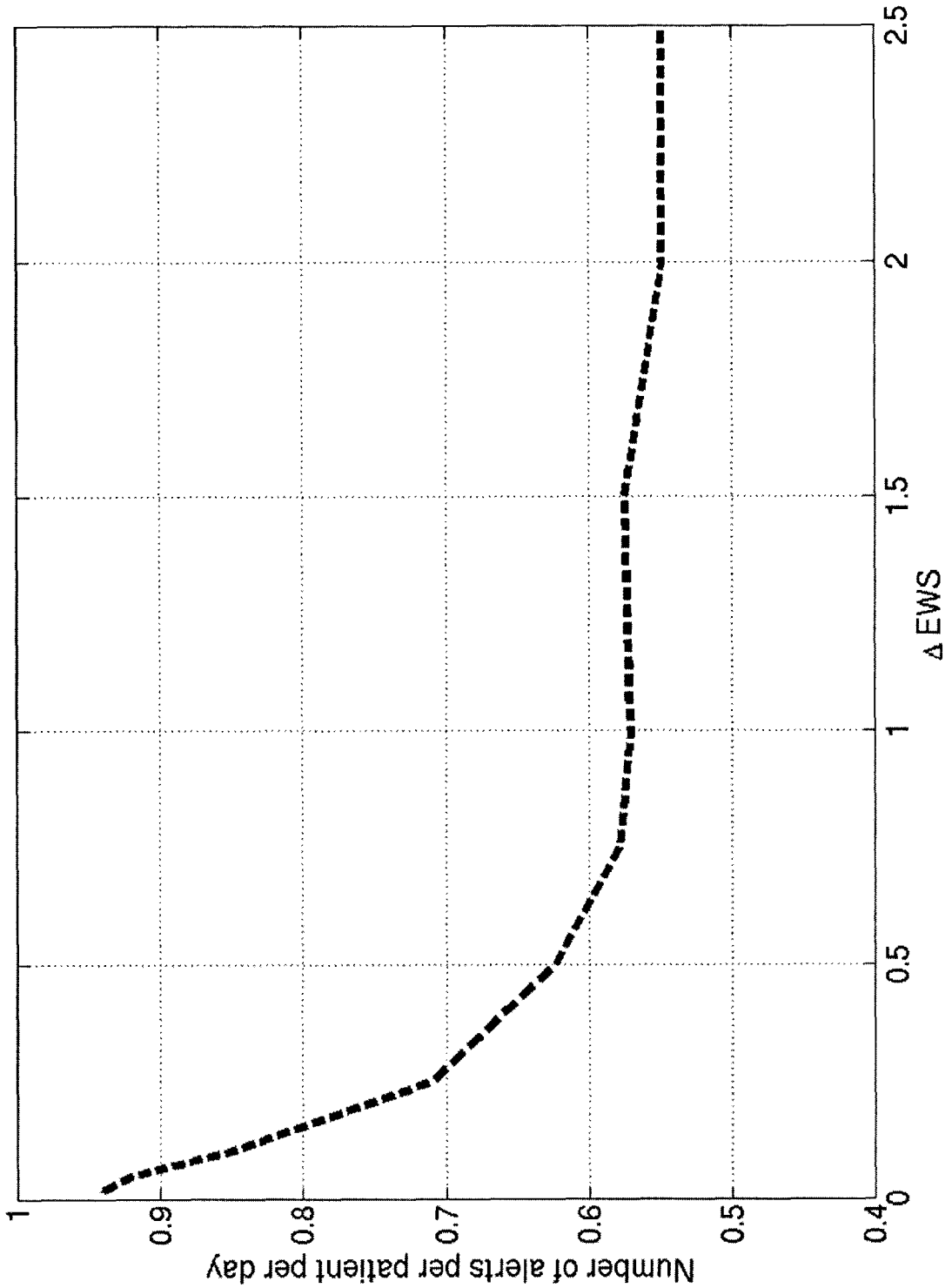
Number of alerts per patient per day
1
0.9
0.8
0.7
0.6
0.5
0.4
0
0.5
1
1.5
2
2.5
Δ EWS

FIG. 8

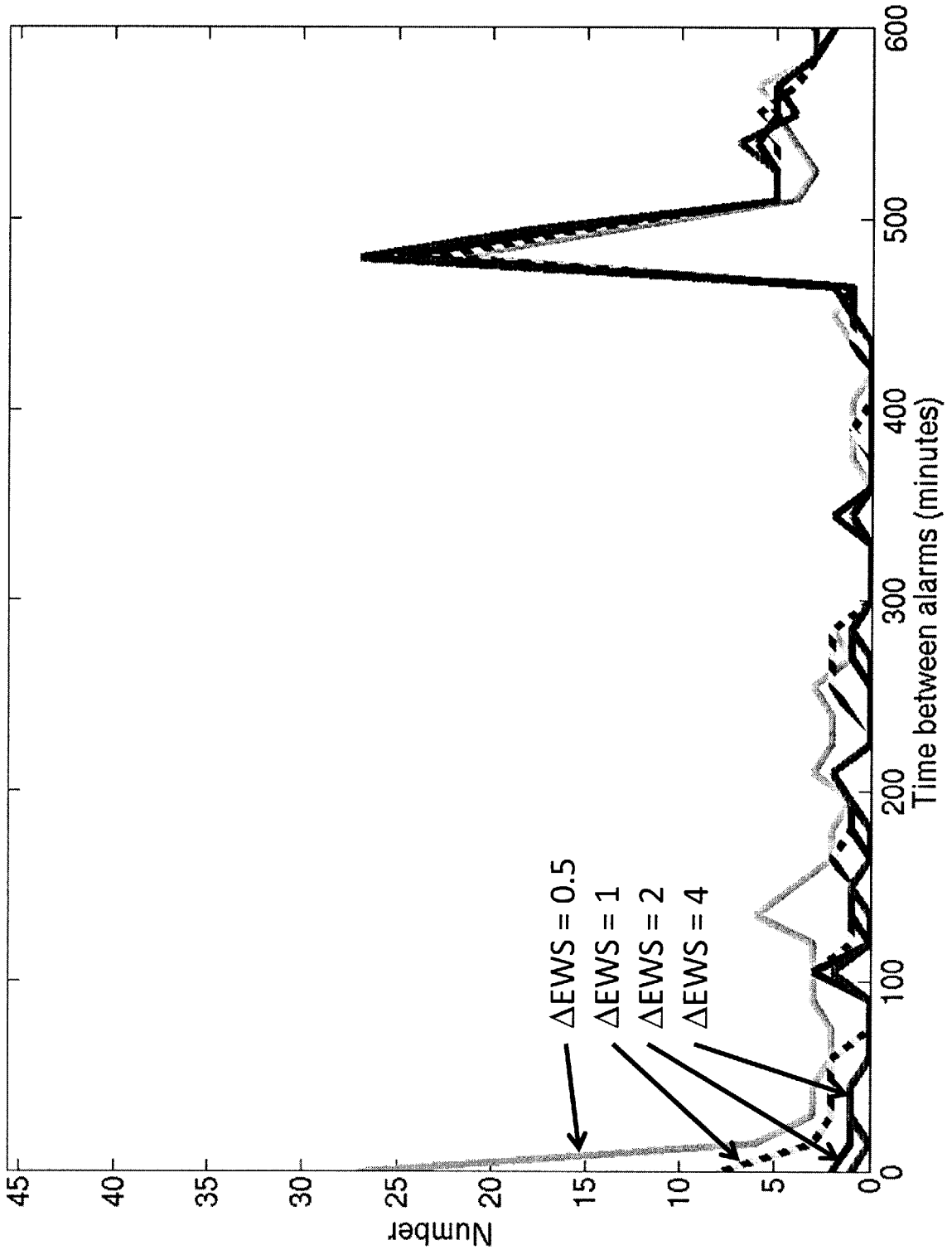
Number
Time between alarms (minutes)
ΔEWS = 0.5
ΔEWS = 1
ΔEWS = 2
ΔEWS = 4
0
5
10
15
20
25
30
35
40
45
0
100
200
300
400
500
600

FIG. 9

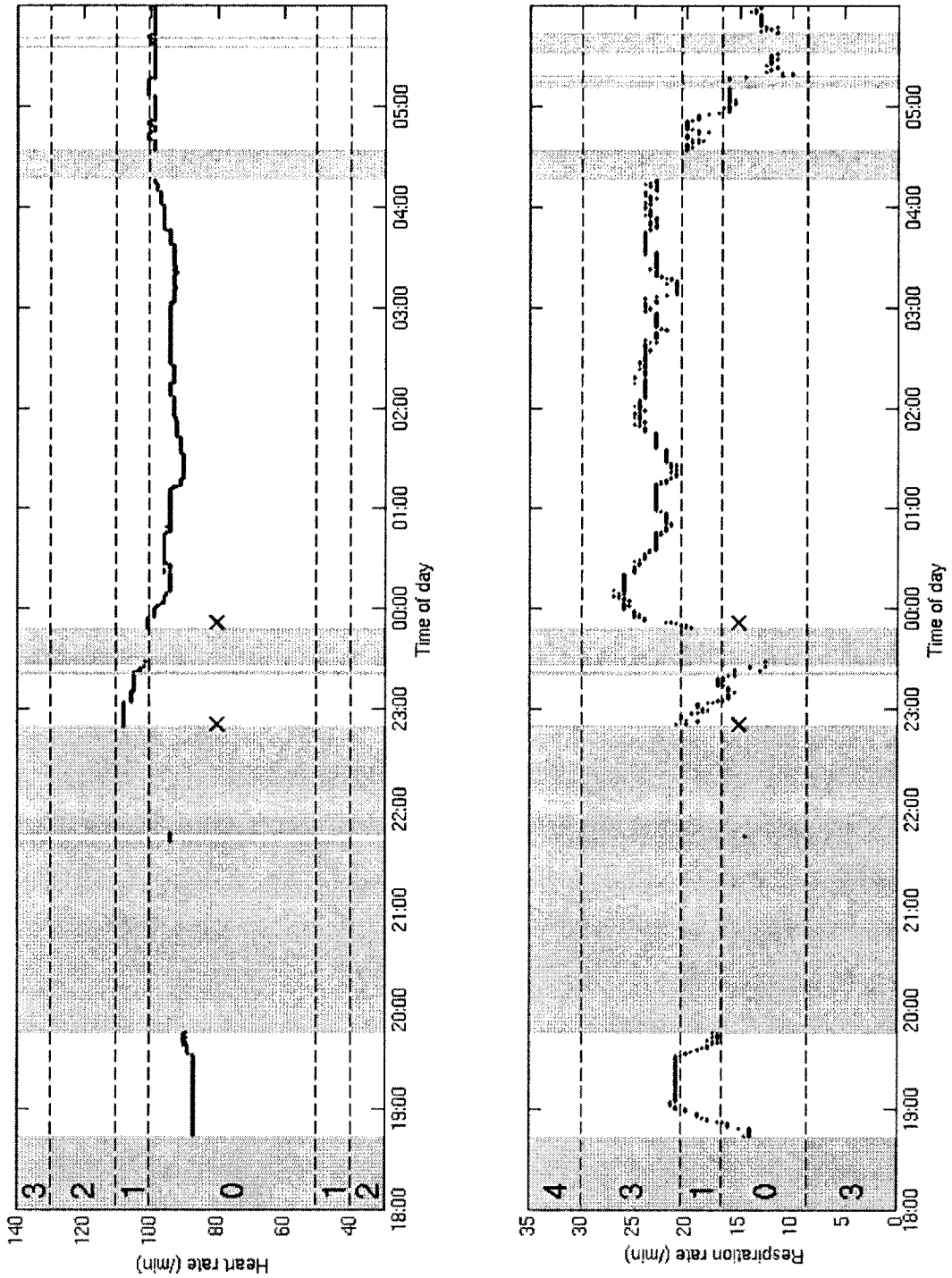
Heart rate (/min)
140
120
100
80
60
40
3
2
1
0
1
2
18:00
19:00
20:00
21:00
22:00
23:00
00:00
01:00
02:00
03:00
04:00
05:00
Time of day
Respiration rate (/min)
35
30
25
20
15
10
5
0
4
3
1
0
3
Time of day

FIG. 10

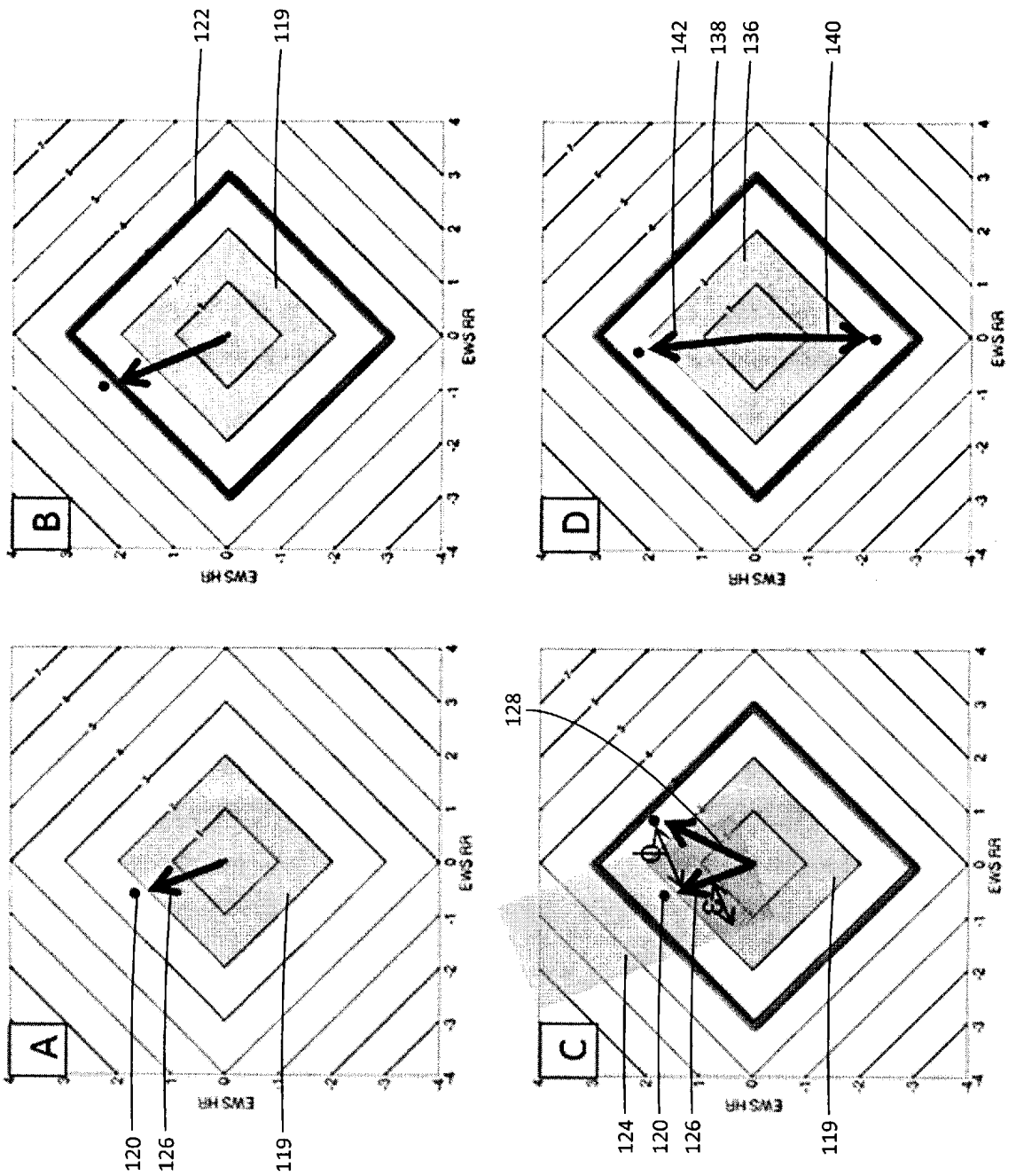

FIG. 11

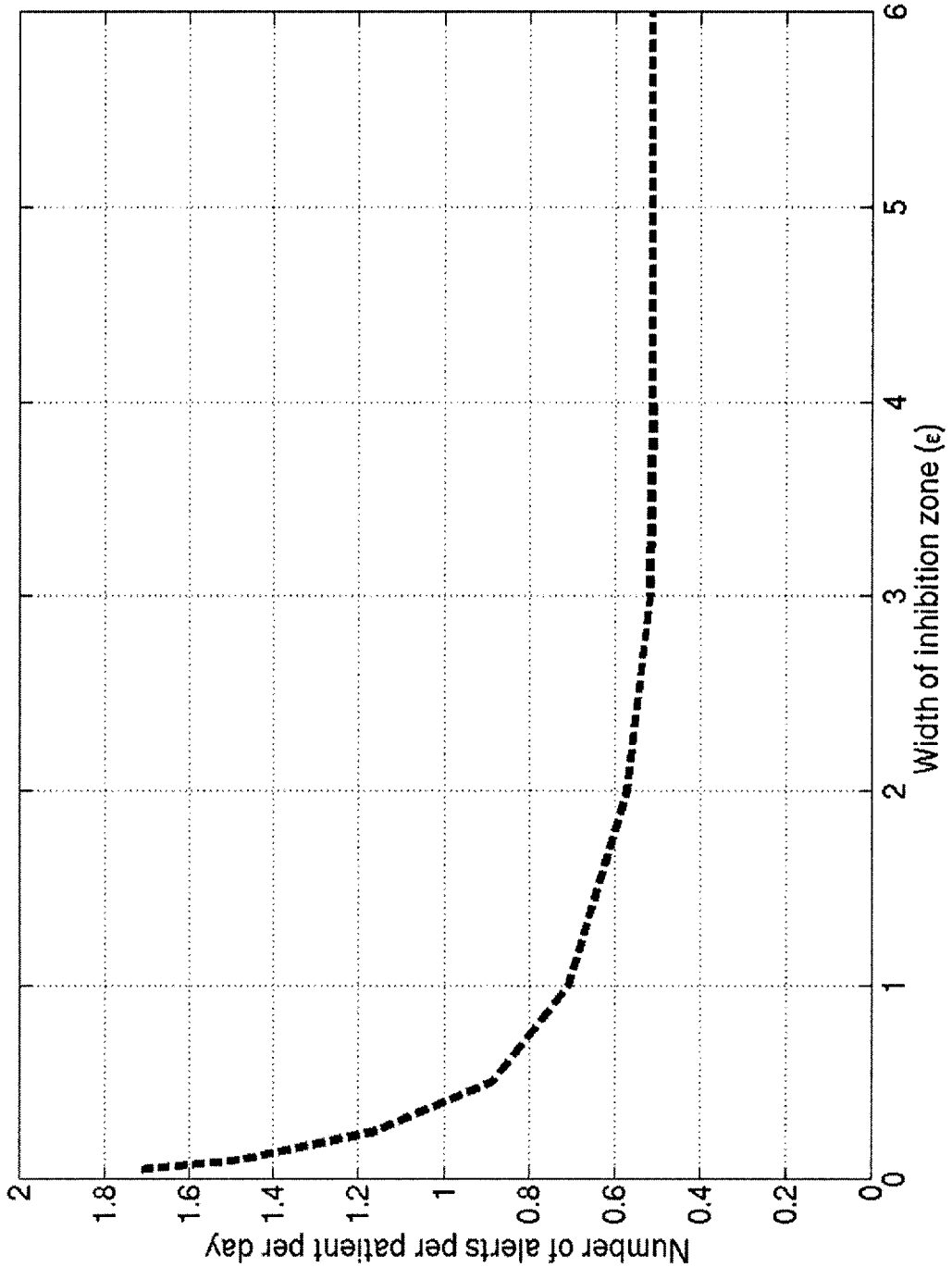
Number of alerts per patient per day
Width of inhibition zone (ε)
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6
1.8
2
0
1
2
3
4
5
6

FIG. 12

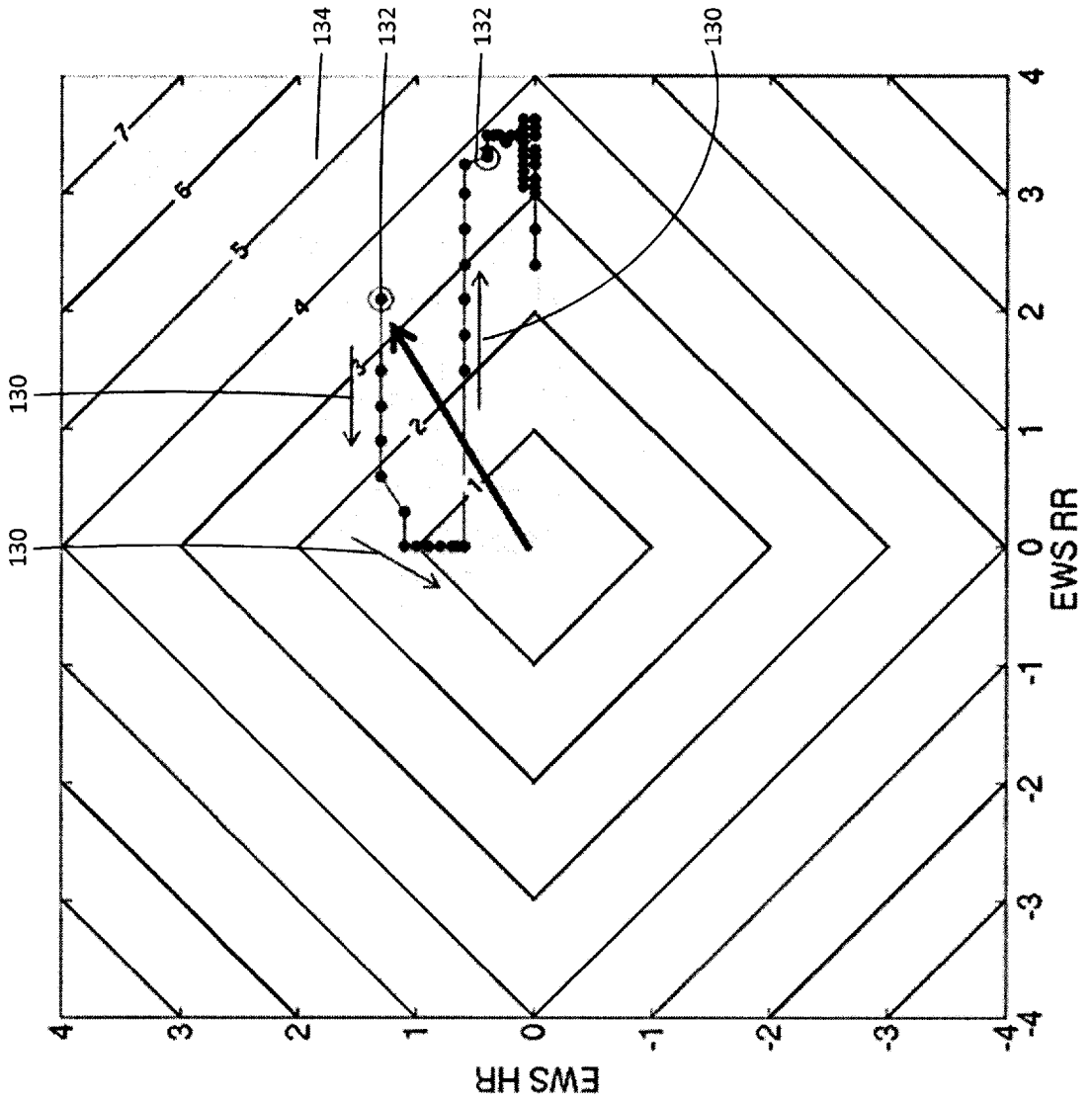

FIG. 13

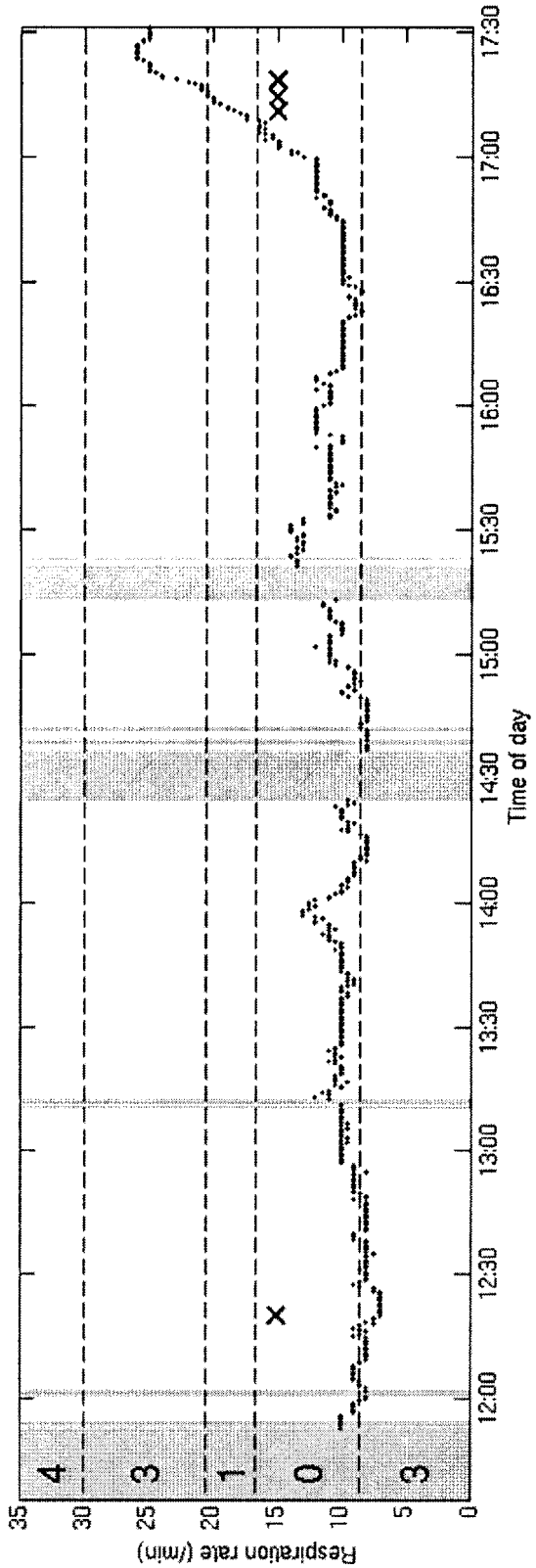
Respiration rate (/min)
Time of day
4
3
1
0
3
35
30
25
20
15
10
5
0
12:00
12:30
13:00
13:30
14:00
14:30
15:00
15:30
16:00
16:30
17:00
17:30

FIG. 14

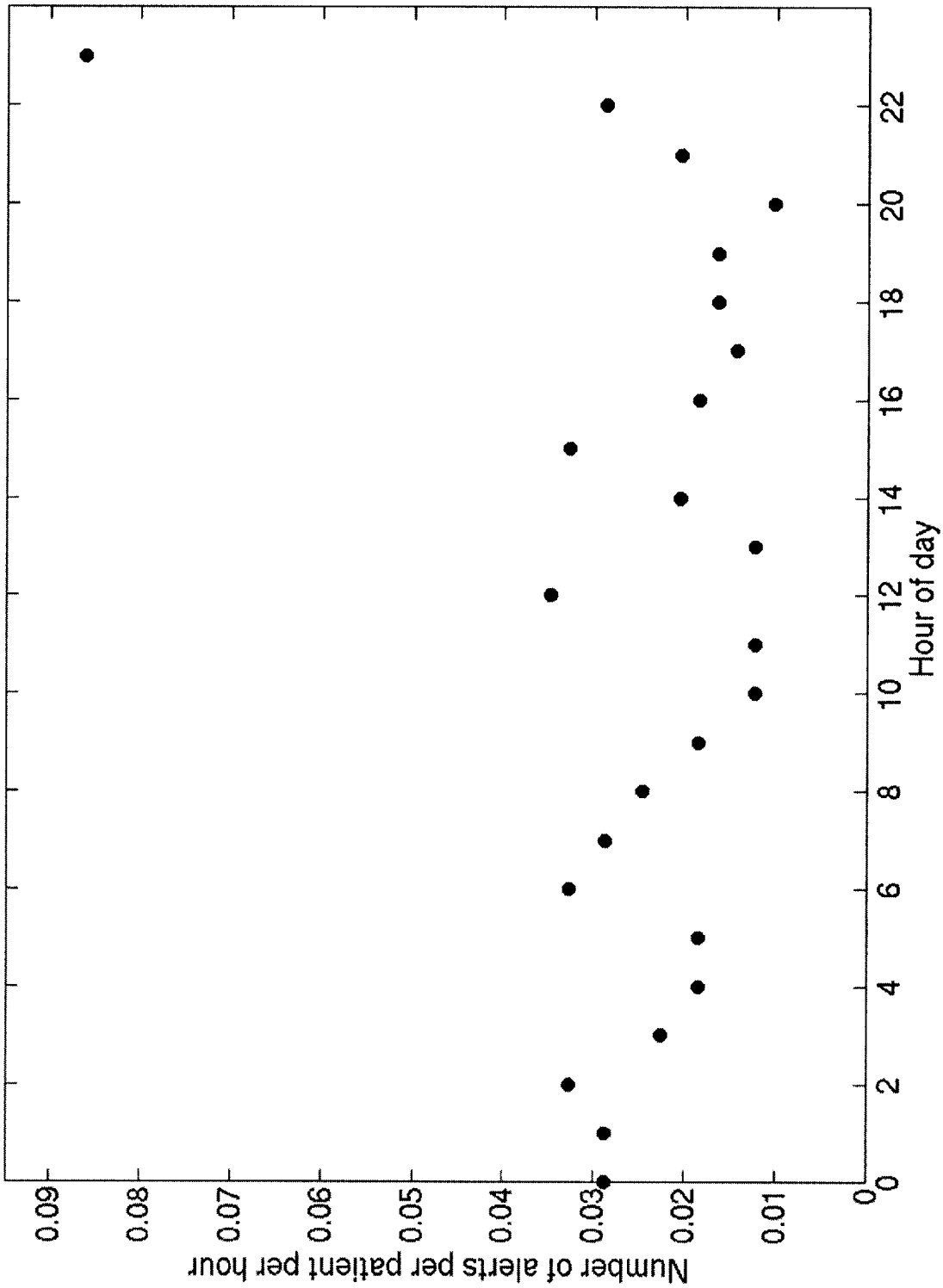
Number of alerts per patient per hour
0.09
0.08
0.07
0.06
0.05
0.04
0.03
0.02
0.01
0
0
2
4
6
8
10
12
14
16
18
20
22
Hour of day

FIG. 15

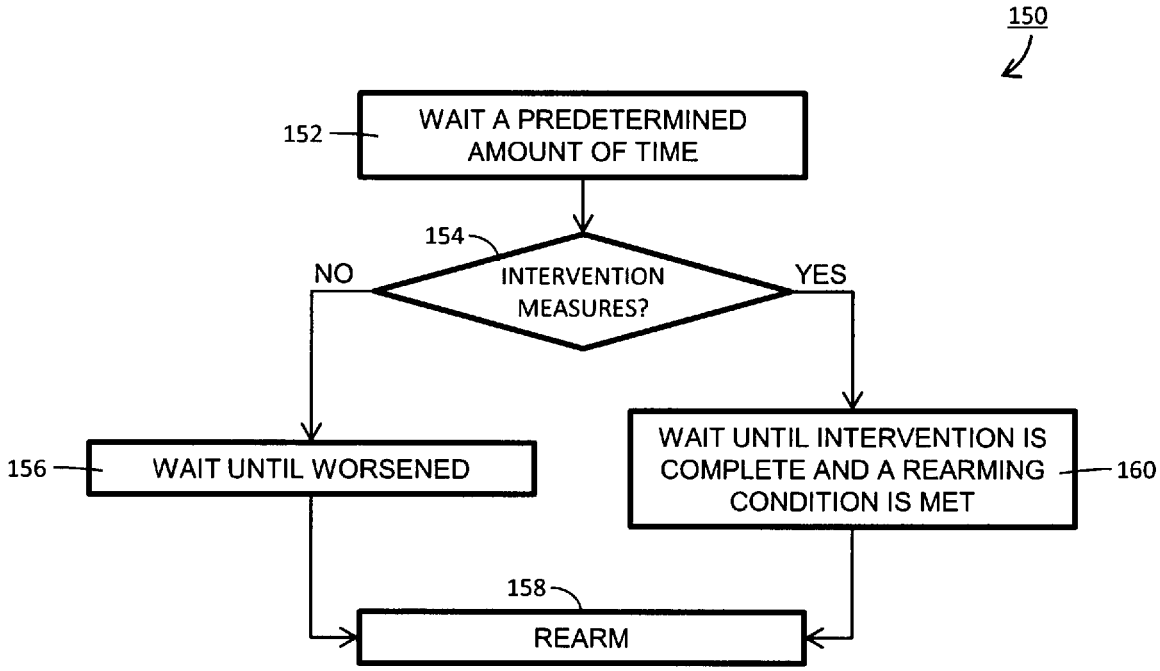
150
152
WAIT A PREDETERMINED AMOUNT OF TIME
154
NO
INTERVENTION MEASURES?
YES
156
WAIT UNTIL WORSENED
WAIT UNTIL INTERVENTION IS COMPLETE AND A REARMING CONDITION IS MET
160
158
REARM

FIG. 16

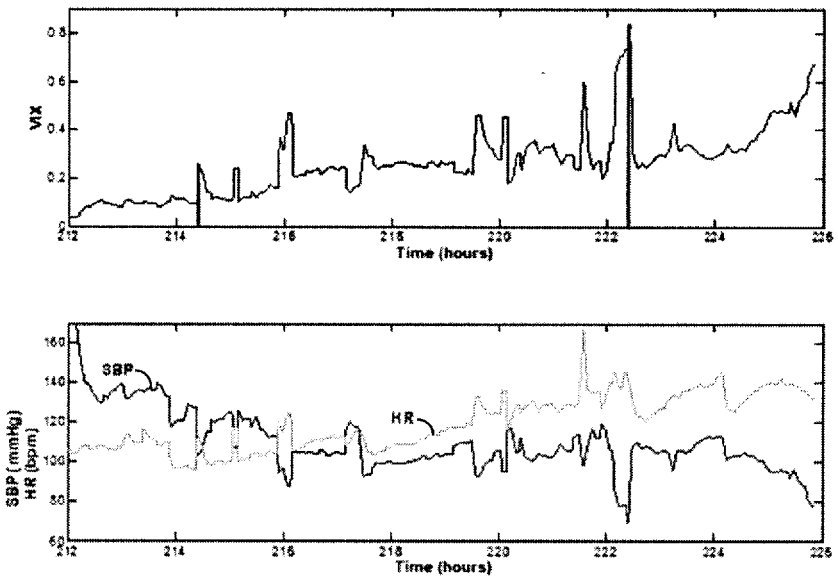
VIX
Time (hours)
SBP
HR
SBP (mmHg)
HR (bpm)
Time (hours)

FIG. 17

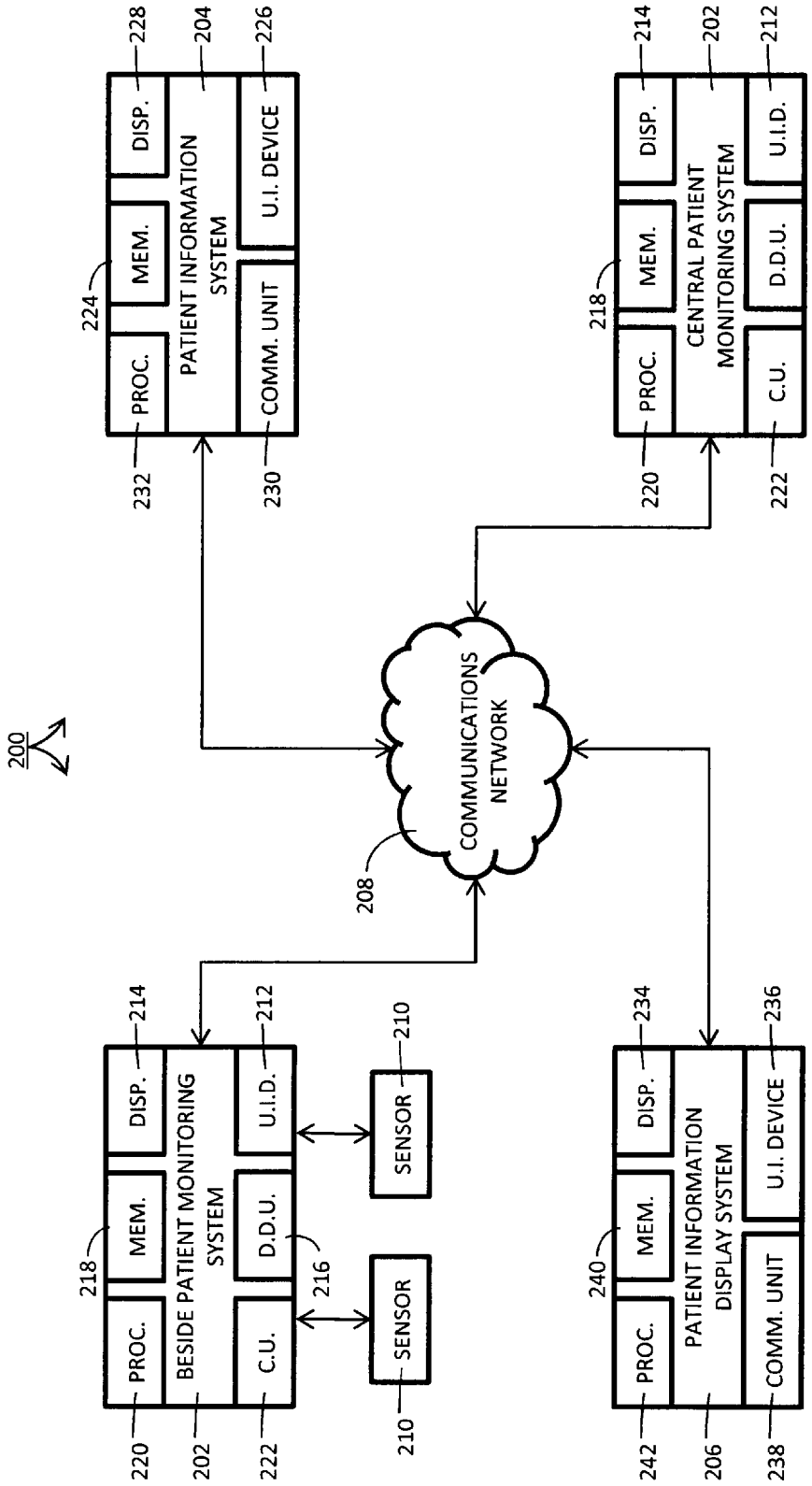
200
COMMUNICATIONS NETWORK
208
PATIENT INFORMATION SYSTEM
PROC.
MEM.
DISP.
COMM. UNIT
U.I. DEVICE
224
232
228
204
230
226
CENTRAL PATIENT MONITORING SYSTEM
PROC.
MEM.
DISP.
C.U.
D.D.U.
U.I.D.
218
220
214
202
222
212
BESIDE PATIENT MONITORING SYSTEM
PROC.
MEM.
DISP.
C.U.
D.D.U.
U.I.D.
218
220
214
202
222
212
216
SENSOR
SENSOR
210
210
PATIENT INFORMATION DISPLAY SYSTEM
PROC.
MEM.
DISP.
COMM. UNIT
U.I. DEVICE
240
242
234
206
238
236

FIG. 18

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- WO 2011007271 A1 **[0012]**
- US 20070232880 A1 **[0013]**

专利名称(译)	用于患者监护仪的阶梯式报警方法		
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[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
申请(专利权)人(译)	皇家飞利浦N.V.		
当前申请(专利权)人(译)	皇家飞利浦N.V.		
[标]发明人	ESHELMAN LARRY JAMES FEDDES BASTIAAN FLOWER ABIGAIL ACTON LAMBERT NICOLAAS LEE KWOK PUN TJAN DAVY HIN TJIANG DE WAELE STIJN GROSS BRIAN DAVID FRASSICA JOSEPH J NIELSEN LARRY SAEED MOHAMMED CAO HANQING		
发明人	ESHELMAN, LARRY, JAMES FEDDES, BASTIAAN FLOWER, ABIGAIL, ACTON LAMBERT, NICOLAAS LEE, KWOK, PUN TJAN, DAVY, HIN, TJIANG DE WAELE, STIJN GROSS, BRIAN, DAVID FRASSICA, JOSEPH, J. NIELSEN, LARRY SAEED, MOHAMMED CAO, HANQING		
IPC分类号	A61B5/1455 G08B21/02 A61B5/00 G08B21/04 G06F19/00		
CPC分类号	A61B5/746 A61B5/14551 G06F19/3418 G08B21/04 G16H40/67 G16H50/20 G08B21/02		
代理机构(译)	STEFFEN，THOMAS		
优先权	61/475453 2011-04-14 US 61/578493 2011-12-21 US		
其他公开文献	EP2696746A1		
外部链接	Espacenet		

摘要(译)

系统（202）使用步进警报方案生成患者警报。系统（202）包括被编程为接收生理分数和/或生理参数值的一个或多个处理器（220）;将生理得分和/或生理参数值与多个警报级别进行比较;响应于落入警报级别的不受禁区内的生理得分和/或生理参数值，发出警报;在发出警报后，为不受限制的警报级别设置第一个禁止期。

$$VIX = \frac{1}{1 + e^{-z'}}$$