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(54) Title: ECG MONITORING WITH REDUCED FALSE ASYSTOLE ALARMS

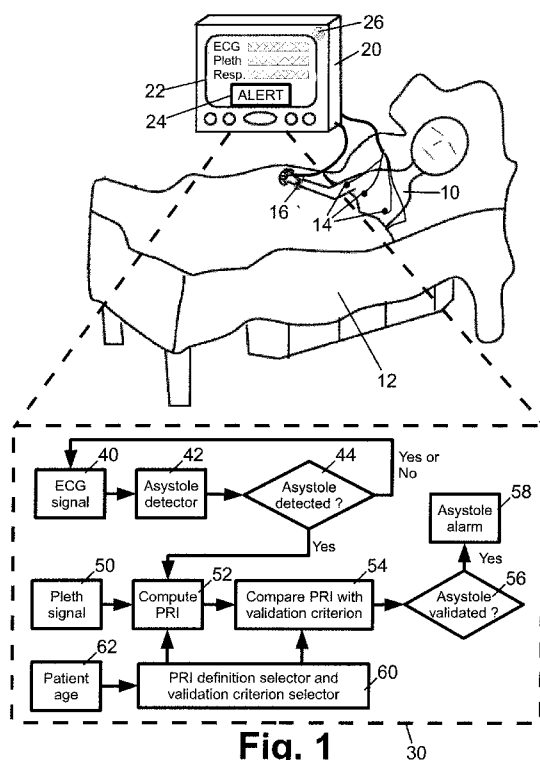


Fig. 1

(57) Abstract: A patient monitor comprises: an electrocardiograph (14, 20) monitoring an electrocardiographic signal (40) of a patient (10); a secondary physiological signal monitor (16, 20) monitoring a second physiological signal (50) of the patient concurrently with the electrocardiograph monitoring the electrocardiographic signal of the patient; an alarm condition detector (42, 44) configured to detect an alarm condition based on the electrocardiographic signal of the patient; an alarm condition validator (52, 54, 56) configured to validate the alarm condition based on pulse regularity of a pulsatile component of the concurrently monitored second physiological signal of the patient; and an alarm indicator (24, 26, 58) configured to generate a human perceptible alarm conditional upon both the alarm condition detector detecting an alarm condition and the alarm condition validator validating the alarm condition.



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ECG MONITORING WITH REDUCED FALSE ASYSTOLE ALARMS

DESCRIPTION

The following relates to the medical arts, medical monitoring arts, physiological monitoring arts, patient safety arts, and related arts.

Electrocardiography (ECG) monitoring is well known as a conventional patient monitoring technique. A skilled cardiologist or other skilled medical diagnostician can infer substantial information from the waveform shape, repetition rate, and other aspects of the ECG signal waveform as a function of time. For more routine patient monitoring, the ECG provides continuous information regarding the heart rate, and a nurse or other medical attendant can identify an urgent patient problem based on large changes in the ECG signal.

Of particular interest for patient monitoring is fast and accurate detection of heart arrhythmias such as ventricular fibrillation or asystole. Ventricular fibrillation is a condition in which the heart loses regulation and begins to beat in a random or pseudorandom fashion – this condition requires immediate attention. Asystole is even more urgent – this is colloquially referred to as a "flatline" condition, in which the heart ceases beating altogether, a condition also known as cardiac arrest. Asystole leads to brain damage and death within minutes, and therefore must be treated immediately. In a hospital or other medical facility detection of asystole initiates a "code blue" event in which a crash team is called to attempt to resuscitate the patient.

ECG advantageously provides fast and generally accurate detection of asystole. It is difficult for ECG to fail to detect asystole, because the ECG monitors the heart rate itself –if the ECG apparatus fails, the result is likely to be a null signal similar to a "flatline" condition, which will result in a code blue event. As a result, ECG is highly unlikely to give a "false negative", that is, to fail to detect a real asystole event.

However, ECG can be susceptible to generating "false positive" events, that is to indicate asystole when in fact the patient's heart is beating normally (or at least is not in asystole). Such false positive events can be triggered by the detachment or other failure of one or more ECG electrodes, caused for example by routine patient movement. Other causes of false positive events include ECG "glitches", signal saturation, or so

forth. Each false positive asystole detection results in medical personnel reacting in an emergency mode, and can trigger an unnecessary code blue event.

It has been estimated that about 90% or more of all asystole detection events are actually false positive events, in which the patient is not undergoing cardiac arrest but the ECG falsely indicates a flatline condition. The costs of these false positive asystole detection events include lost time of medical professionals responding to the false event, stress on all medical professionals in the area, stress on the patient who finds his or her medical monitor suddenly emitting a loud audible alarm or otherwise indicating an emergency condition, and desensitization of medical personnel to the point where they may fail to respond in an appropriately urgent fashion to an actual patient cardiac arrest.

On the other hand, the cost of a single false negative asystole detection event is that the patient may suffer brain damage or death due to delay in providing medical assistance to the patient undergoing cardiac arrest.

Attempts have been made to reduce the number of false positive asystole detection events by analyzing the ECG signal, or by augmenting the ECG signal with other concurrently acquired patient monitoring information such as arterial blood pressure. For example, Aboukhalil et al., "Reducing false alarm rates for critical arrhythmias using arterial blood pressure waveform", Journal of Biomedical Informatics vol. 41, pp. 442-51 (2008) discloses an approach in which the ECG signal is augmented by arterial blood pressure (ABP) pulsing rate. In this approach, the asystole alarm is suppressed if the pulse-to-pulse interval for the ABP signal is shorter than a threshold value. This approach assumes the APB pulsing rate correlates with the cardiac cycle, so that if the ABP pulsing interval is shorter than the threshold value then the APB pulses correspond to cardiac cycling, indicating that the flatline ECG must be in error.

Problematically, existing techniques for reducing false positive asystole detection events also substantially increase the likelihood of generating a false negative event so as to "miss" a real asystole event. For example, the approach of Aboukhalil et al. could potentially suppress a real asystole detection alarm if noise or artifacts in the APB signal were to produce a sequence of APB pulses at intervals below the threshold value.

The following provides new and improved apparatuses and methods which overcome the above-referenced problems and others.

In accordance with one disclosed aspect, a patient monitor comprises: an electrocardiograph monitoring an electrocardiographic signal of a patient; a secondary physiological signal monitor monitoring a second physiological signal of the patient concurrently with the electrocardiograph monitoring the electrocardiographic signal of the patient; an alarm condition detector configured to detect an alarm condition based on the
5 electrocardiographic signal of the patient; an alarm condition validator configured to validate the alarm condition based on pulse regularity of a pulsatile component of the concurrently monitored second physiological signal of the patient; and an alarm indicator configured to generate a human perceptible alarm conditional upon both the alarm
10 condition detector detecting an alarm condition and the alarm condition validator validating the alarm condition

In accordance with another disclosed aspect, a patient monitoring method comprises: monitoring an electrocardiographic signal of a patient; monitoring a second physiological signal of the patient concurrently with the monitoring of the
15 electrocardiographic signal of the patient; detecting an alarm condition based on the electrocardiographic signal of the patient; validating the alarm condition based on pulse regularity of a pulsatile component of the concurrently monitored second physiological signal of the patient; and generating a human perceptible alarm conditional upon the alarm condition being validated by the validating.

20 In accordance with another disclosed aspect, a storage medium is disclosed which stores instructions executable by a digital processor to perform a patient monitoring method as set forth in the immediately preceding paragraph.

One advantage resides in providing a reduction in false positive asystole detection events without concurrent suppression of false negative asystole detection events.

25 Another advantage resides in providing a substantial reduction in false positive asystole events thus enhancing accuracy of ECG-based asystole event detection.

Further advantages will be apparent to those of ordinary skill in the art upon reading and understand the following detailed description.

FIGURE 1 diagrammatically shows a patient monitoring system with
30 detection and validation of asystole events.

FIGURE 2 diagrammatically shows the pulse regularity index (PRI) computation component of FIGURE 1 in additional detail.

FIGURE 3 diagrammatically shows a plethysmogram (pleth) signal along with a pulse regularity index (PRI) computed from the pleth signal.

FIGURE 4 diagrammatically shows a three-channel ECG signal, a concurrently monitored plethysmogram (pleth) signal, and a pulse regularity index (PRI) computed from the pleth signal, for a time interval including two true asystole events.

FIGURE 5 diagrammatically shows a three-channel ECG signal, a concurrently monitored plethysmogram (pleth) signal, and a pulse regularity index (PRI) computed from the pleth signal, for a time interval including one false asystole event.

It is disclosed herein to validate ECG asystole event alarms based on rhythm and amplitude information of a secondary physiological signal such as an arterial blood pressure signal or plethysmogram signal. The disclosed validation technique not only utilizes instant pulse-to-pulse interval of the secondary physiological signal, but also incorporates a short-term pulse regularity feature to verify ECG asystole events. A pulse regularity index (PRI) is disclosed, which summarizes, on a beat-by-beat basis, the short-term secondary physiological signal pulse rhythm and amplitude feature in terms of regularity. The PRI value represents the extent of short-term pulse regularity and is used to validate ECG asystole alarms.

Regular pulses (in terms of rhythm and amplitude) do not happen during asystole. Regular pulses are also unlikely to be generated by random noise or artefacts. Accordingly, the disclosed validation approach employing the PRI has high reliability in keeping true ECG asystole alarms while rejecting false ECG asystole alarms. The PRI is computed on a beat-by-beat basis at least during an ECG asystole alarm. The PRI value computed for the last pulse detection cycle (prior to the asystole event) is checked for validating the asystole alarm. This processing is therefore computationally efficient and provides fast validation of the ECG asystole alarm.

With reference to FIGURE 1, a patient **10** is disposed on a bed **12** or, alternatively, may be standing, sitting, in an ambulance or other emergency response vehicle, or otherwise disposed. Although the illustrated patient **10** is a human patient, it is also contemplated for the patient to be an animal, such as in a veterinary setting. Electrodes **14** are attached to the patient **10** in order to acquire electrocardiographic (ECG) signals. A sensor **16** detects a secondary physiological signal. For example, the sensor **16** may be a

pulse oxymeter mounted on a finger, toe, or other part of the patient **10**, or other sensor detecting a plethysmogram (pleth) signal, or an arterial blood pressure (ABP) sensor, or other blood pressure sensor, or so forth. The sensor **16** detects a secondary physiological signal (that is, other than the ECG signal detected by the electrodes **14**). The secondary
5 physiological signal exhibits a pulsatile signal component with substantial regularity in pulse interval and pulse amplitude during the normal physiological condition.

A patient monitor **20** monitors the ECG signal detected by the ECG electrodes **14**, and monitors the pleth signal, ABP signal, or other secondary physiological signal detected by the sensor **16**. In other words, the patient monitor **20** serves as both an
10 electrocardiograph that monitors the ECG signal and as a secondary physiological signal monitor that monitors the pleth signal, ABP signal, or other secondary physiological signal detected by the sensor **16**. Alternatively, a separate electrocardiograph and secondary physiological signal monitor may be provided (not illustrated). The patient monitor **20** includes a display **22** that displays one or more monitored physiological parameters, such
15 as the ECG signal, the plethysmogram (pleth) signal, and a respiration signal in the illustrative example of FIGURE 1.

The patient monitor **20** further includes one or more alarm indicators for generating a human-perceptible alarm during an alarm condition, such as an illustrative visual alarm indicator **24** that is shown on the display **22** during an alarm condition
20 (preferably in a distinctive and noticeable manner such as flashing, in red, or so forth), and an illustrative speaker **26** that generates an audible alarm during an alarm condition. Alarm conditions that may be visually and audibly indicated by the elements **24**, **26** include at least an asystole event, and may optionally include other life- or health-threatening events such as a ventricular fibrillation event, a respiratory failure, or so forth. In addition to or
25 alternative to the illustrative alarm indicators **24**, **26**, it is contemplated for an alarm condition to be indicated by a remote indicator located at a nurses' station (not shown). A single alarm indicator type (either visual or audible) is also contemplated.

A digital processor **30** is provided to process monitored physiological signals such as the monitored ECG signal and the monitored ABP, pleth, or other
30 secondary physiological signal, in order to detect and validate an alarm condition. The digital processor **30** may be variously located and embodied, and may comprise two or more digital processors. In the illustrative embodiment, the digital processor **30** is a

component of the patient monitor **20**; alternatively or additionally, the digital processor may be disposed at a nurses' station and embodied as a computer that receives and processes physiological signals monitored by the patient monitor **20**, or so forth. As another example, the digital processor may include a first processor disposed in the patient
5 monitor **20** that acquires the ECG and second physiological signals and performs alarm detection, and a second digital processor disposed in a computer of the nurses' station which performs alarm validation.

It is also to be appreciated that the alarm detection and validation techniques disclosed herein can be suitably embodied as a storage medium storing instructions
10 executable by the digital processor **30** to perform the disclosed alarm detection and validation techniques. Such a storage medium may, for example, comprise one or more of the following: a hard disk or other magnetic storage medium; an optical disk or other optical storage medium; a random access memory (RAM), read-only memory (ROM), flash memory, or other electrical or electrostatic storage medium; or so forth.

As illustrated in FIGURE 1, the digital processor **30** is configured to detect and validate an ECG alarm. A detected ECG signal **40** is processed by an asystole detector **42** to detect a "flatline" condition in which the ECG signal does not exhibit pulsatile behavior indicative of a beating heart. At a decision block **44** it is determined whether asystole has been detected based on the ECG signal **40** alone. Regardless of whether
20 asystole is detected, the processing blocks **40**, **42**, **44** cycle repetitively in order to provide continuous ECG signal monitoring for an asystole condition. This is indicated by the loopback arrow in FIGURE 1 labeled with the decision "Yes or No".

If at the decision block **44** it is determined that an asystole event has been detected based on the ECG signal **40** alone (indicated by the arrow in FIGURE 1 labeled
25 with the decision "Yes"), the asystole alarm condition is validated based on a pleth signal **50** that is monitored by the plethysmogram implemented by the patient monitor **20** and sensor **16**. The illustrative pleth signal **50** may be replaced by an APB signal or other secondary physiological signal that exhibits a pulsatile signal component with substantial regularity in pulse interval and pulse amplitude during the normal physiological condition.
30 To validate the asystole alarm generated by the ECG alone, the pleth signal **50** (or other secondary physiological signal with a pulsatile component that is not an ECG signal) is processed by a pulse regularity index (PRI) computation block **52** to generate a pulse

regularity index (PRI) quantifying pulse regularity of the pulsatile component of the monitored second physiological signal **50**. The computed PRI is compared in a comparison block **54** with a validation criterion. Based on this comparison, an asystole alarm validation block **56** decides whether the asystole alarm generated by the ECG alone should be validated. If the asystole alarm is validated, then a human-perceptible asystole alarm **58** is issued, for example by activating the audio speaker **26** to emit an audibly perceptible asystole alarm, and/or by showing the visually perceptible alarm indicator **24** on the display **22** of the patient monitor **20**, or by activating an audible and/or visual alarm at a nurses' station (not shown), or so forth.

The validation criterion is suitably determined by training the detecting and validating operations respective to a training set of ECG signals and second physiological signals concurrently acquired from a plurality of calibration patients, in which the training set has asystole conditions labeled. For example, based on this training a threshold value is suitably determined for the PRI such that every actual asystole event is properly validated (no false negatives) and a substantial number of asystole alarm events generated by the ECG alone are invalidated by comparison of the PRI with the trained threshold value. In some embodiments, the training may be performed for patients of different characteristics in order to generate different validation criteria for different classes of patients. For example, the illustrated embodiment of FIGURE 1 was trained for different age classes (e.g., infant age class, pediatric age class, adult age class, elderly age class) and a PRI definition and validation criterion selector **60** selects the PRI definitions for use in the compute PRI block **52** and the validation criterion for use in the comparison block **54** based on an inputted patient age **62**. Adjustment for different patient classes can take the form of adjustment of the threshold criterion, or adjustment of the definition of the quantitative PRI formula or definition, or both.

With reference to FIGURE 2, an illustrative implementation of the pulse regularity index (PRI) computation block **52** is described as an illustrative example. In general, the PRI computation entails a pulse detector **70** which detects pulses of the pulsatile component of the secondary physiological signal, and a PRI computation **80** based on pulse amplitude and pulse interval information for the detected pulses. In the illustrated embodiment of FIGURE 2, the PRI is calculated on a pulse-by-pulse basis for a current pulse based on the current pulse and N immediately preceding pulses. The value of

the positive integer N is selected to provide sufficient information for a meaningful estimate of the pulse amplitude and pulse interval regularity at the time of the current pulse, but should be short enough to provide a PRI that is not unduly influenced by substantially earlier pulsatile behaviour. In general, N should be greater than or equal to two, and in some embodiments is greater than or equal to three. In some illustrative examples, $N=4$ is used, so that the $N+1$ pulses analyzed (including the current pulse and the N immediately preceding pulses) constitute five pulses in total. Assuming the pulsatile signal is consonant with a heart rate of around 60-150 beats per minute, $N+1=5$ pulses amounts to between about two seconds and five seconds worth of information. Again, other values for N may be used. For each current pulse, a PRI is computed based on the rhythm and amplitude features derived from the current pulse and the immediately preceding N pulses. To validate an ECG asystole alarm, only the PRI from the current pulse just before, at, or just after the asystole alarm event is checked in order to validate the asystole alarm event.

In general, the pulse detection **70** can consider either peak or onset of the pulse as the fiducial point for the pulse time. In illustrative FIGURE 2, the pulse detection **70** is performed using a method similar to that described in Zong et al., "An open-source algorithm for detection of ABP pulse onset", Computers in Cardiology, 29:345-48 (2003), which is incorporated herein by reference in its entirety. This method uses pulse onset as the fiducial point. The monitored pleth signal **50** is filtered by a low-pass filter **72**, for example having a cutoff frequency of about 15 Hz (although other cutoff frequencies are contemplated). The low-pass filtered pleth signal is then converted to a slope-sum function (SSF) signal by a slope-sum function **74**, which facilitates the pulse onset detection. An adaptive threshold and local search **76** is applied to SSF signal to find the pulse and a local search process locates the onset of the pulse.

A problem can arise, however, if the secondary physiological signal **50** does not have a pulsatile component. This might indeed be expected, for example, during an actual asystole event. To address this situation, a forced pulse detection **78** is provided, which defines one or more pulses of the set of $N+1$ pulses as a forced pulse detection conditional upon the pulsatile component of the monitored second physiological signal **50** having no pulses in a preselected time interval. That is, when no pulse is detected for more than 2 seconds (or for another preselected time interval) since the last detected pulse, a

forced pulse detection is defined as one of the N+1 pulses. The forced pulse detection is labelled as such so that it is specially treated during the PRI computation **80**. Alternatively, it is contemplated to assign a forced pulse detection a default amplitude and default pulse interval (relative to its nearest-neighbor pulses).

5 The PRI generation operation **80** takes the time series of N+1 pulses as input. In this illustrative PRI computation example, any forced pulse detection generated by the operation **78** is treated as same as the normal pulse detection for the later on pulse interval and amplitude feature analysis. For each pulse (including, in this example, any forced pulse detection), pulse amplitude and interval information is computed as statistical
10 pulse-to-pulse (PP) interval features and statistical pulse amplitude features analyzed over the N+1 pulses. The PP interval and amplitude statistics can be done in the following way: For the current pulse denoted P_i and the N immediately preceding pulses denoted P_{i-n} , $n = 1, \dots, N$, calculate the following variables: (i) number of the forced-detections denoted FD_{NUM} ; (ii) mean value of the pulse-to-pulse interval (PPI) denoted PPI_{MEAN} ; (iii) standard
15 deviation of the PPI denoted PPI_{SD} ; (iv) mean value of the N+1 pulse amplitudes denoted PPA_{MEAN} ; and (iv) standard deviation of the N+1 pulse amplitudes denoted PPA_{SD} .

In this illustrative PRI computation example, fuzzy variables are used to represent the statistical features of the pulse amplitude and interval information. The following three fuzzy variables are defined: ' $PPI_{MEAN_is_Reasonable}$ ', ' $PPI_{SD_is_Small}$ ',
20 and ' $PPA_{SD_is_Small}$ '. Standard functions, namely the S-function and the Z-function, are used as the membership functions. The S-function and Z-function are defined as follows:

$$S(x; a, b) = \begin{cases} 0 & , \quad x \leq a \\ 2 \cdot \left(\frac{x-a}{b-a} \right)^2 & , \quad a < x \leq \frac{a+b}{2} \\ 1 - 2 \cdot \left(\frac{x-b}{b-a} \right)^2 & , \quad \frac{a+b}{2} < x \leq b \\ 1 & , \quad b < x \end{cases} \quad (1),$$

and

$$Z(x; a, b) = 1 - S(x; a, b) \quad (2).$$

25 Using the S-function and Z-function as membership functions, the fuzzy variables are defined as follows for this illustrative PRI computation example:

$$\begin{aligned} & \text{'PPI}_{MEAN_is_Reasonable} \text{' (PPI-Mean-R)} \\ \mu_{PPI-Mean-R} &= S(PPI_{MEAN}; 200, 400) \wedge Z(PPI_{MEAN}; 1500, 2000) \end{aligned} \quad (3),$$

where PPI_{MEAN} is the mean value of the PPI among the considered N+1 pulse detections; the unit of the parameters is ms; and operator $\wedge$ is the standard fuzzy intersection: $\mu_A \wedge \mu_B = \min [\mu_A, \mu_B]$. ' $PPI_{SD_is_Small}$ ' can be defined using Z-function as the membership function:

5

$$\begin{aligned} & \text{'PPI}_{SD_is_Small} \text{' (PPI-SD-S)} \\ & \mu_{PPI-SD-S} = Z(PPI_{SD}/PPI_{MEAN}; 0.1, 0.2) \end{aligned} \quad (4)$$

where PPI_{SD} is the standard deviation of the PPI among the considered N+1 pulse detections. " $PPA_{SD_is_Small}$ " can be defined using the Z-function as the membership function:

10

$$\begin{aligned} & \text{'PPA}_{SD_is_Small} \text{' (PPA-SD-S)} \\ & \mu_{PPA-SD-S} = Z(PPA_{SD}/PPA_{MEAN}; 0.1, 0.2) \end{aligned} \quad (5)$$

where PPA_{SD} is the standard deviation of the pulse-by-pulse amplitude (PPA) and PPI_{MEAN} is the mean value of the PPA, among the considered N+1 pulse detections. In addition, a binary variable, " $No_Forced_Detections$ " is defined using the Boolean function:

15

$$\begin{aligned} & \text{'No_Forced_Detections' (NFD)} \\ & \mu_{NFD} = \text{Boolean}('FD_{Count} == 0') \end{aligned} \quad (6),$$

where, FD_{Count} is the number of the forced-detections among the considered N+1 pulse detections; $\text{Boolean}(\text{True}) = 1$, $\text{Boolean}(\text{False}) = 0$. A composite fuzzy variable, " $Pulses_are_Regular$ ", is derived from the following fuzzy logic reasoning (i.e., fuzzy conditional statement):

20

$$\begin{aligned} & \text{IF } \text{'No_Forced_Detections' AND} \\ & \quad \text{'PPI}_{MEAN_is_Reasonable' AND} \\ & \quad \text{'PPI}_{SD_is_Small' OR 'PPA}_{SD_is_Small'} \\ & \text{THEN 'Pulses_are_Regular'} \end{aligned} \quad (7)$$

25

$$\mu_{\text{'Pulses_are_Regular'}} = \mu_{NFD} \wedge \mu_{PPI\text{-}mean\text{-}R} \wedge (\mu_{PPI\text{-}SD\text{-}S} \vee \mu_{PPA\text{-}SD\text{-}S})$$

where μ_{NFD} , $\mu_{PPI\text{-}mean\text{-}R}$, $\mu_{PPI\text{-}SD\text{-}S}$, and $\mu_{PPA\text{-}SD\text{-}S}$ are from Equations (3)-(6), and the operator $\vee$ is the standard fuzzy union: $\mu_A \vee \mu_B = \max [\mu_A, \mu_B]$. The fuzzy variable " $Pulses_are_Regular$ " has a value between 0 and 1 with the value 1 representing the best short-term pulse regularity and the value 0 representing the worst short-term pulse

30

regularity (that is, substantially no pulse regularity). The PRI value is assigned to the value of fuzzy variable '*Pulses_are_Regular*':

$$PRI = \mu_{Pulses_are_Regular} \quad (8).$$

5

The illustrative PRI computation works in the following way: For a secondary physiological signal (e.g., the illustrative pleth signal **50**, or an APB signal), the onset (or, alternatively, the peak or other fiducial) of each pulse is detected. If there is no pulse detectable for more than 2 seconds (or another preselected time interval), then a forced pulse detection is applied. For each detected pulse (or forced pulse detection), a value of the PRI is computed according to Equation (8) and is associated with the pulse. The PRI indicates short-term pulse regularity associated to the pulse, where "short term" is defined by the time interval of the N+1 pulses including the current pulse which are taken into consideration in computing the PRI.

15 The above PRI definition is for the class of adult patients. For patients of other classes (for example, pediatric patients) the PRI definition selector and validation criterion selector may adjust the PRI value, or the threshold criterion, or both in order to provide useful validation operation for these patients.

20 With reference to FIGURE 3, an example of the illustrative PRI computation is displayed. The top trace of FIGURE 3 shows the source pleth signal, while the bottom trace of FIGURE 3 shows the PRI computed using Equation (8), with N=4. Each vertical line in FIGURE 3 denotes a pulse onset. A single forced pulse detection was employed, as denoted by the label "F" on the vertical line corresponding to the forced pulse detection. As expected, the PRI has a value of unity (1) in regions where the pleth signal has a visually manifest regularity, and the PRI decreases to a value of zero (0) in the central region of FIGURE 3 where the regularity of the pleth signal has visually manifest irregularity.

30 With reference back to FIGURE 1, in comparison block **54** the PRI is compared with the validation criterion to validate the asystole alarm generated by the ECG. At a time *i* when an ECG asystole alarm is issued, the PRI associated with the last pulse prior to or synchronous with time *i* is compared with the validation criterion. For the illustrative PRI computation example, the validation criterion is suitably a validation

threshold denoted Thr – if the PRI is greater than the validation threshold Thr (that is, $PRI > Thr$), then the asystole alarm generated by the ECG alone is rejected as a false alarm; otherwise, the asystole alarm is accepted as a true alarm at decision block **56**, and the human-perceptible asystole alarm **58** is activated.

5 In the illustrated embodiments, there is only one secondary physiological signal (the illustrated pleth signal **50**) for use in the validation. If two (or more) secondary physiological signals are available for the validation, they can be used by computing a PRI for each secondary physiological signal and choosing one of the computed PRI. For the example case in which a larger PRI indicates more pulse regularity, the validation criterion
10 is suitably a threshold which must be exceeded in order to override the ECG asystole alarm. In this case, the maximum PRI computed from the two available secondary physiological signals (for example, both pleth and ABP signals available) is suitably used in the comparison block **54**.

 The window size N and the validation threshold Thr can be optimized using
15 set of training data with annotated ECG asystole alarms and their associated ECG and secondary physiological (e.g., ABP or Pleth) signals. In an actually conducted training session, $N=4$ and $Thr=0.5$ were selected by the training. For the training, an annotated dataset of 65 records was used, of which all records have pleth signal data and 11 records also have ABP signal data). This training set was selected from 756 intensive care unit
20 patients, and provides a total of 1916 hours (with an average of 28 hours/record) of continuous ECG signal and concurrent ABP and/or Pleth signals. The training set included 147 asystole alarms as indicated by ECG alone. Of these 147 alarms, 15 alarms were true positives (that is, actual asystole events) and 132 were false positives as judged by human expert. The trained validation system using only the pleth signal for validation rejected
25 46% of the false ECG asystole alarms without rejecting any of the 15 true asystole alarm events. When the ABP signal (when available) was used to replace the pleth signal in the validation system, 52% of false ECG asystole alarms were overridden, again without rejecting any true asystole alarm event. When using both ABP (when available) and pleth,
30 59% of false ECG alarms were rejected, again without rejecting any true asystole alarm event.

 With reference to FIGURE 4, an example is shown where a true ECG asystole alarm was properly kept (that is, validated as true alarm) by the validation system

of FIGURE 1 trained as described herein. The topmost three traces show a three-channel ECG. Two (true) asystole alarms were issued by the ECG-based asystole detector, as indicated by the thick vertical lines that pass through the three-channel ECG traces. The second-from bottom trace is the concurrently acquired pleth signal, while the bottommost trace is the PRI computed from the pleth signal. When ECG asystole happened, the pleth signal lost regularity and the computed PRI decreased to zero, even though there were still pulsations due to respiration in the pleth signal. At the time of each of the two (true) ECG asystole alarms, it is observed that the PRI value is low (essentially zero) and lower than $Thr=0.5$ which was the trained threshold, both ECG asystole alarms are validated as true positive asystole alarms. In the bottom two plots, lighter vertical lines that pass through only the lowermost two curves (that is, the pleth and PRI curves) indicate the pulse onset detections. Three forced pulse detections are indicated by vertical lines labelled by "F".

With reference to FIGURE 5, an example of a false ECG asystole alarm is shown, which was rejected (that is, not validated) by the validation system of FIGURE 1 trained as described herein. The topmost three traces show a three-channel ECG. A single (false) asystole alarm was issued by the ECG-based asystole detector, as indicated by the thick vertical line passing through the three-channel ECG traces. The second-from bottom trace is the concurrently acquired pleth signal, while the bottommost trace is the PRI computed from the pleth signal. The false ECG asystole event was issued due to the reduced amplitude of the ECG signals. However, the pleth signal continued to behave regularly during this ECG asystole event, and the computed PRI remained at 1 indicating a high degree of pulsatile regularity. At the onset of the (false) ECG asystole event, the PRI was larger than the trained $Thr=0.5$, and so the ECG asystole alarm was rejected (that is, was not validated).

In the foregoing illustrative embodiments, the alarm condition is an asystole alarm condition that is detected using the ECG and validated based on quantification of pulse regularity of the secondary physiological signal (e.g., pleth and/or APB signal). However, other alarm conditions can be detected and validated using the disclosed techniques. For example, a ventricular fibrillation alarm event is readily detected from the ECG signal. Validation of a detected ventricular fibrillation event similarly can be validated based on quantification of pulse regularity of the secondary physiological signal (e.g., pleth and/or APB signal) as disclosed herein. For validation of a ventricular

fibrillation alarm event, it is contemplated that it may be advantageous to employ additional noise rejection filtering, since a ventricular fibrillation alarm event does not entail complete stoppage of heart pulsations but rather randomization of heart pulsations. The training of the validation criterion for validating ventricular fibrillation alarm events
5 should employ training data with ventricular fibrillation alarm events labeled, either alone or in addition to labeling of asystole events (if present in the training data).

This application has described one or more preferred embodiments. Modifications and alterations may occur to others upon reading and understanding the preceding detailed description. It is intended that the application be construed as including
10 all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

CLAIMS

Having thus described the preferred embodiments, the invention is now claimed to be:

1. A patient monitor comprising:
 - an electrocardiograph (14, 20) monitoring an electrocardiographic signal (40) of a patient (10);
 - a secondary physiological signal monitor (16, 20) monitoring a second physiological signal (50) of the patient concurrently with the electrocardiograph monitoring the electrocardiographic signal of the patient;
 - an alarm condition detector (42, 44) configured to detect an alarm condition based on the electrocardiographic signal of the patient;
 - an alarm condition validator (52, 54, 56) configured to validate the alarm condition based on pulse regularity of a pulsatile component of the concurrently monitored second physiological signal of the patient; and
 - an alarm indicator (24, 26, 58) configured to generate a human-perceptible alarm conditional upon both the alarm condition detector detecting an alarm condition and the alarm condition validator validating the alarm condition.
2. The patient monitor as set forth in claim 1, wherein the alarm condition detector (42, 44) is configured to detect an asystole alarm condition.
3. The patient monitor as set forth in any one of claims 1-2, wherein the secondary physiological signal monitor (16, 20) is selected from a group consisting of:
 - an arterial blood pressure (ABP) monitor monitoring arterial blood pressure of the patient concurrently with the electrocardiograph (14, 20) monitoring the electrocardiographic signal of the patient, and
 - a plethysmogram monitoring a plethysmogram signal of the patient concurrently with the electrocardiograph monitoring the electrocardiographic signal of the patient.

4. The patient monitor as set forth in any one of claims **1-3**, wherein the alarm condition validator (**52, 54, 56**) is configured to (i) compute a pulse regularity index (PRI) (**52**) quantifying pulse regularity of the pulsatile component of the monitored second physiological signal and (ii) validate the alarm condition based on the PRI satisfying a validation criterion (**54, 56**).

5. The patient monitor as set forth in claim **4**, wherein the alarm condition validator (**52, 54, 56**) is configured to compute the pulse regularity index (PRI) (**52**) based on a set of N+1 pulses including (i) a current pulse of the pulsatile component of the monitored second physiological signal (**50**) and (ii) N immediately preceding pulses of the pulsatile component of the monitored second physiological signal, where N is a positive integer greater than or equal to two.

6. The patient monitor as set forth in claim **5**, wherein the alarm condition validator (**52, 54, 56**) is configured to compute the pulse regularity index (PRI) (**52**) based on (i) amplitude information for the pulses of the set of N+1 pulses and (ii) time interval information between the pulses of the set of N+1 pulses.

7. The patient monitor as set forth in any one of claims **5-6**, wherein the alarm condition validator (**52, 54, 56**) is configured to define one or more pulses of the set of N+1 pulses as a forced pulse detection (**78**) conditional upon the pulsatile component of the monitored second physiological signal (**50**) having no pulses in a preselected time interval.

8. The patient monitor as set forth in any one of claims **4-7**, wherein the alarm condition validator (**52, 54, 56**) is configured to select (**60**) at least one of (i) a definition of the PRI and (ii) the validation criterion based on patient age (**62**).

9. The patient monitor as set forth in any one of claims **4-8**, wherein:
the secondary physiological signal monitor (**16, 20**) monitors at least two different second physiological signals of the patient concurrently with the electrocardiograph monitoring the electrocardiographic signal of the patient; and

the alarm condition validator (**52, 54, 56**) is configured to compute the pulse regularity index (PRI) (**52**) for each of the at least two different second physiological

signals and to validate the alarm condition based whether the largest computed PRI satisfies the validation criterion.

10. The patient monitor as set forth in any one of claims **1-9**, wherein the alarm condition validator (**52, 54, 56**) is configured to extract the pulsatile component of the monitored second physiological signal from the monitored second physiological signal using signal processing including at least low pass filtering (**72**).

11. A patient monitoring method comprising:
monitoring an electrocardiographic signal (**40**) of a patient (**10**);
monitoring a second physiological signal (**50**) of the patient concurrently with the monitoring of the electrocardiographic signal of the patient;
detecting an alarm condition based on the electrocardiographic signal of the patient;
validating the alarm condition based on pulse regularity of a pulsatile component of the concurrently monitored second physiological signal of the patient; and
generating a human-perceptible alarm (**24, 26, 58**) conditional upon the alarm condition being validated by the validating.

12. The patient monitoring method as set forth in claim **11**, further comprising:
determining the validation criterion based on training the detecting and validating operations respective to a training set of electrocardiographic signals and second physiological signals concurrently acquired from a plurality of calibration patients wherein the training set has asystole conditions labeled.

13. The patient monitoring method as set forth in any one of claims **11-12**, wherein the detecting comprises:
detecting an asystole alarm condition based on the electrocardiographic signal (**40**) of the patient (**10**).

14. The patient monitoring method as set forth in any one of claims **11-13**, wherein the validating comprises:

detecting (70) N+1 pulses including a current pulse and N immediately preceding pulses of the pulsatile component of the concurrently monitored second physiological signal (50) of the patient (10) where N is a positive integer greater than or equal to two;

computing a pulse regularity index (PRI) (80) quantifying pulse regularity of the N+1 detected pulses; and

comparing the PRI with a validation criterion (54, 56).

15. The patient monitoring method as set forth in claim **14**, wherein the detecting (70) N+1 pulses comprises:

detecting at least one of the N+1 pulses as a forced pulse detection (78) conditional upon a failure to detect a pulse.

16. The patient monitoring method as set forth in any one of claims **14-15**, wherein N is a positive integer greater than or equal to three.

17. The patient monitoring method as set forth in any one of claims **14-16**, wherein the computing a pulse regularity index (PRI) (80) comprises:

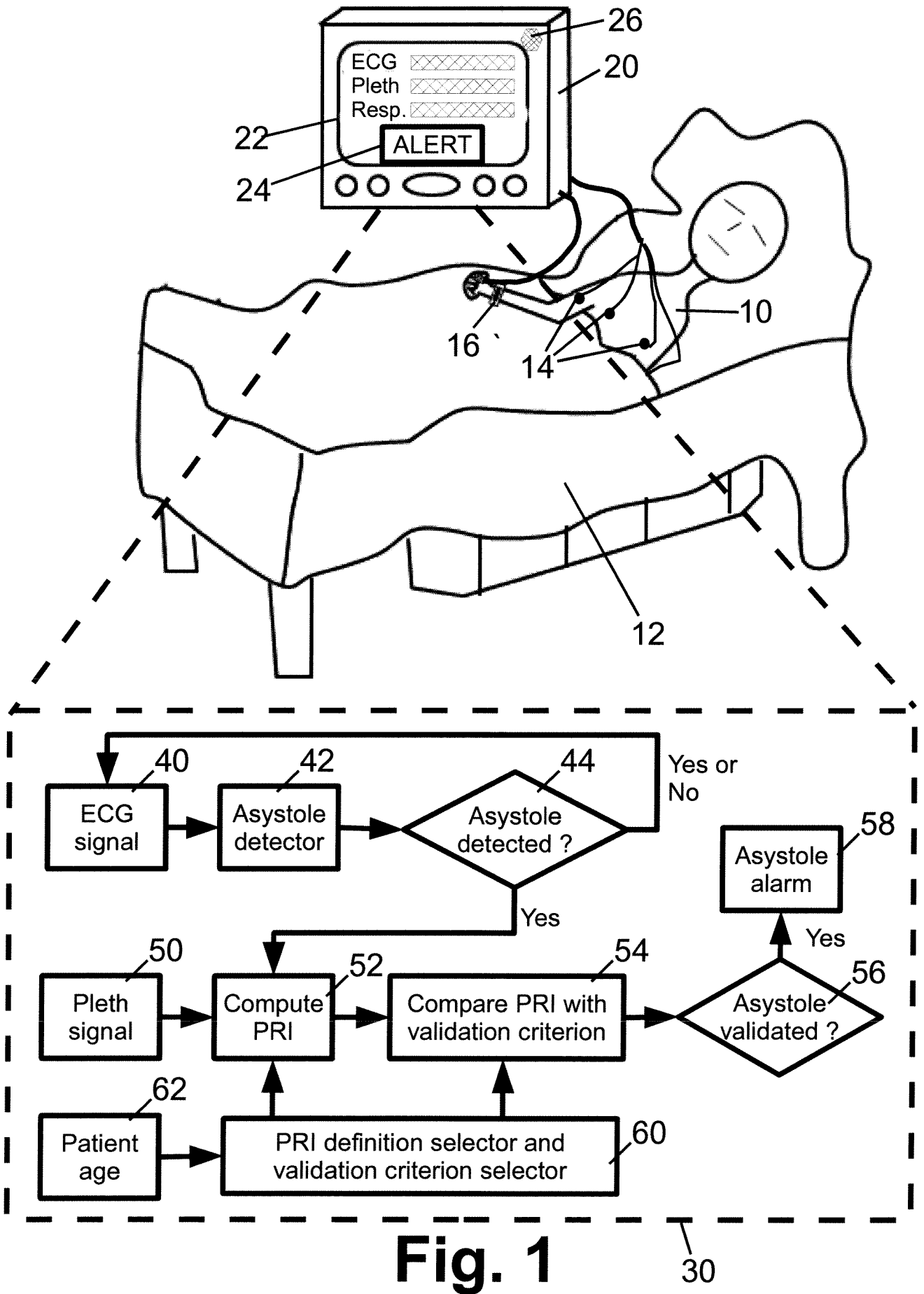
computing the PRI based on both (i) amplitudes of the N+1 pulses and (ii) intervals between successive pulses of the N+1 pulses.

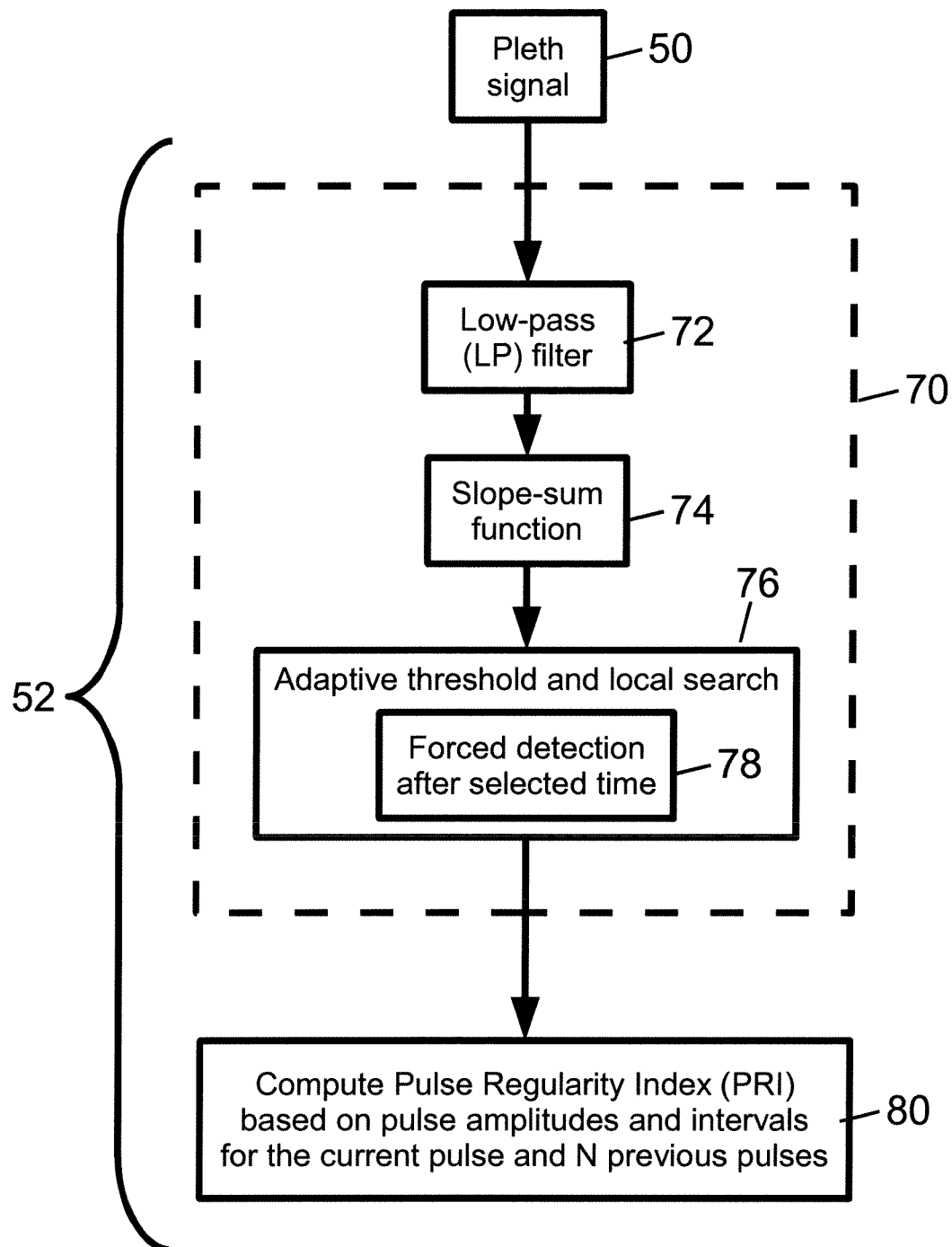
18. The patient monitoring method as set forth in any one of claims **11-17**, wherein the validating comprises:

validating the alarm condition based on pulse regularity including both pulse amplitude regularity and pulse interval regularity of the pulsatile component of the concurrently monitored second physiological signal (50) of the patient (10).

19. The patient monitoring method as set forth in claim **18**, wherein the validating is further based on a mean or average pulse interval of the pulsatile component of the concurrently monitored second physiological signal (50) of the patient (10).

20. A storage medium storing instructions executable by a digital processor (30) to perform a patient monitoring method as set forth in any one of claims **11-19**.



**Fig. 2**

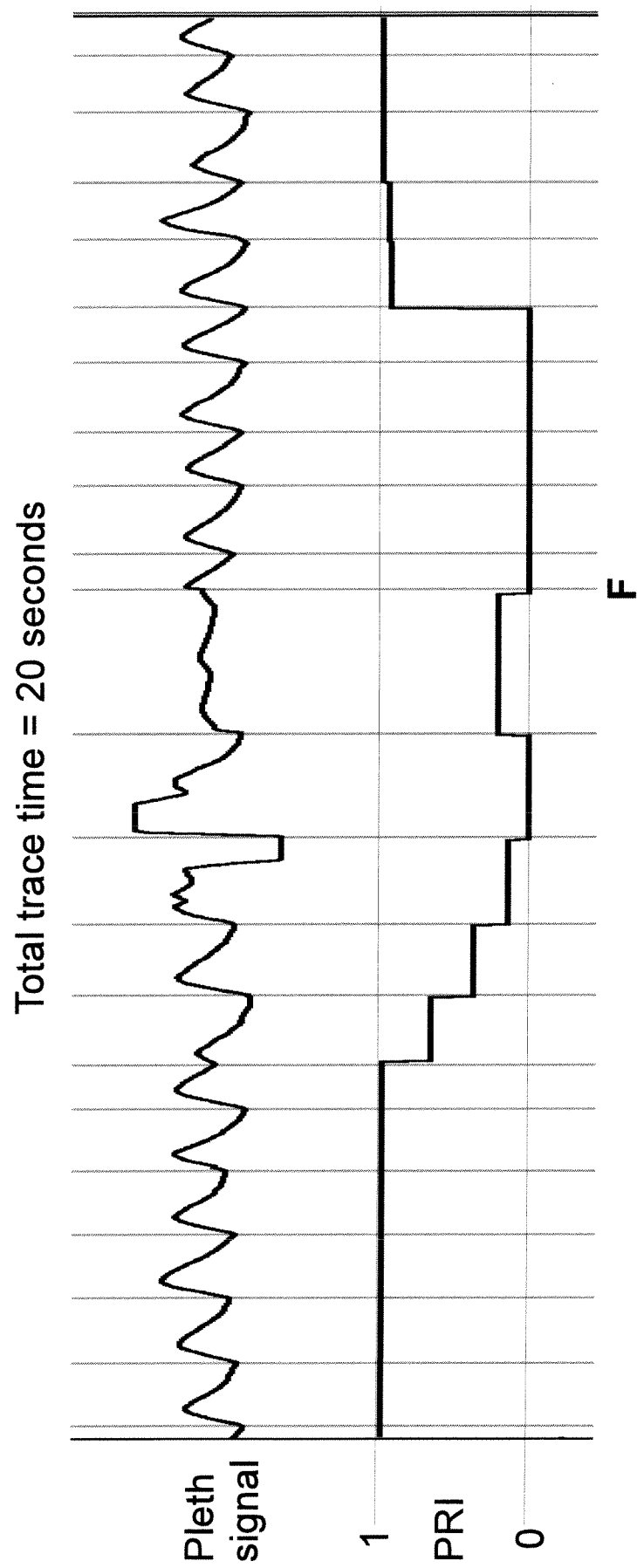


Fig. 3

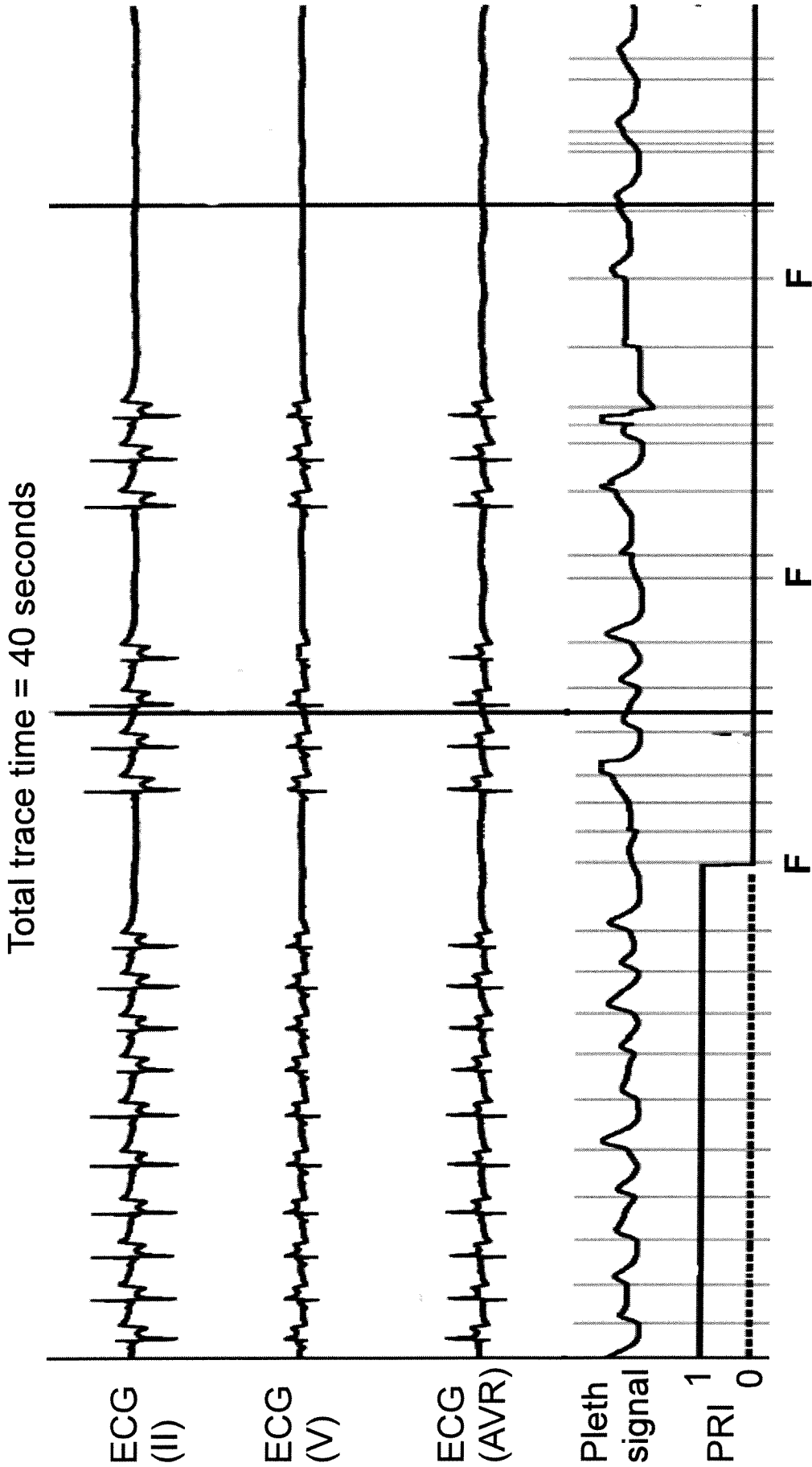


Fig. 4

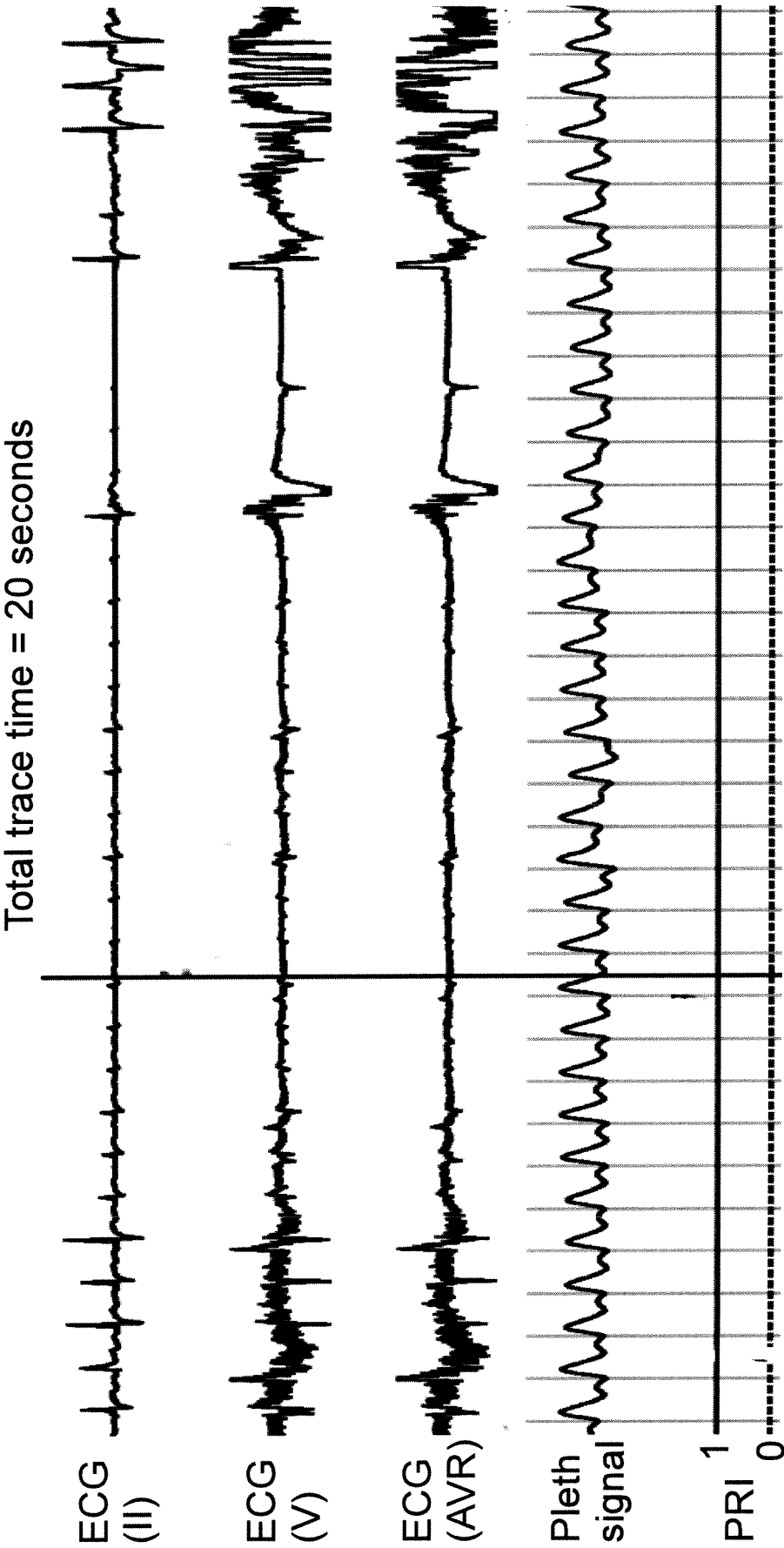


Fig. 5

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2010/052123

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/0452

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

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

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

EPO-Internal, BIOSIS, COMPENDEX, INSPEC, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents :

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

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"P" document published prior to the international filing date but later than the priority date claimed

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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

30 September 2010

Date of mailing of the international search report

13/10/2010

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INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2010/052123

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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A	ZONG W ET AL: "REDUCTION OF FALSE ARTERIAL BLOOD PRESSURE ALARMS USING SIGNAL QUALITY ASSESSMENT AND RELATIONSHIPS BETWEEN THE ELECTROCARDIOGRAM AND ARTERIAL BLOOD PRESSURE" MEDICAL AND BIOLOGICAL ENGINEERING AND COMPUTING, SPRINGER, HEILDELBURG, DE LNKD-DOI:10.1007/BF02347553, vol. 42, no. 5, 1 September 2004 (2004-09-01), pages 698-706, XP001221025 ISSN: 0140-0118 page 699, right-hand column, paragraph 4 - page 700, left-hand column, paragraph 1 page 701, left-hand column, paragraph 2 - page 703, left-hand column, paragraph 1 figures 2,6,7 -----	1,11,20
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Information on patent family members

International application No

PCT/IB2010/052123

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