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(54) **METHOD AND APPARATUS FOR DISTINGUISHING BETWEEN CLINICALLY SIGNIFICANT CHANGES AND ARTIFACTS IN PATIENT PHYSIOLOGICAL INFORMATION**

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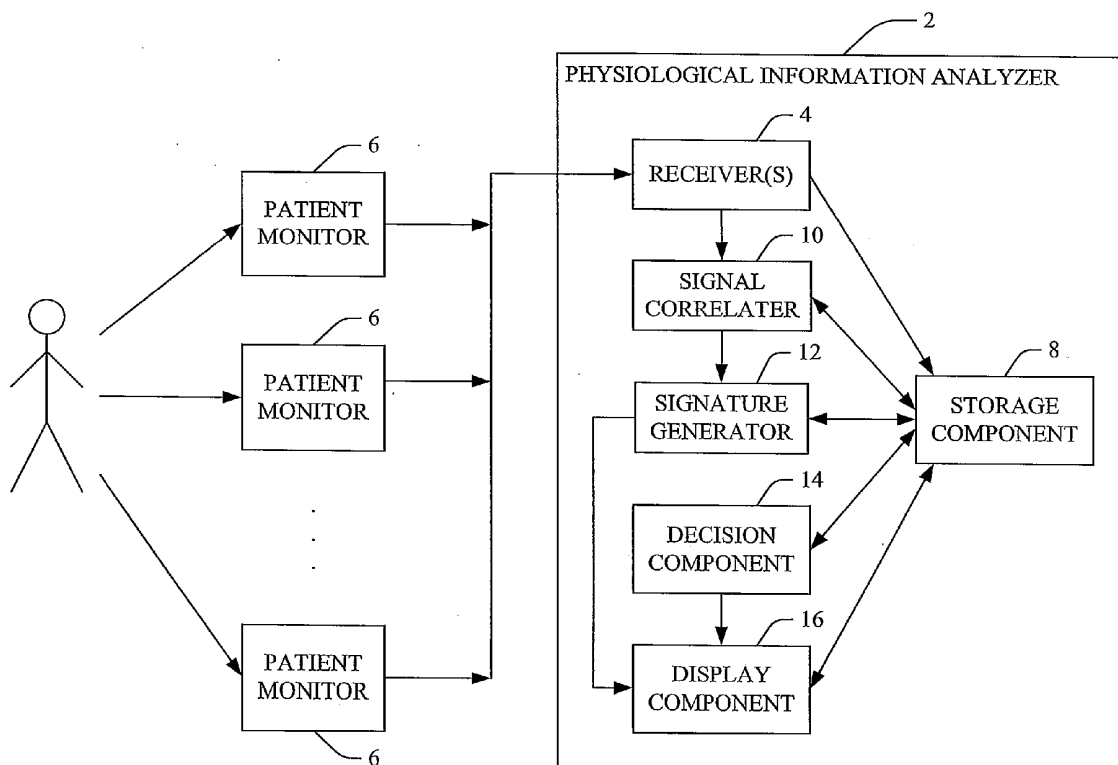
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(52) **U.S. Cl.** **600/301; 705/2**
(57) **ABSTRACT**

A patient physiological information monitoring system includes a plurality of patient monitoring devices (6) and a physiological information analyzer (2). The plurality of patient monitoring devices (6) monitor physiological information from a patient and generate corresponding physiological signals. The physiological information analyzer (2) processes the monitored physiological information and determines whether a physiological change is a clinically significant event or an artifact. The physiological information analyzer includes at least one receiver (4) that receives the physiological signals from the patient monitoring devices; a signal correlator (10) that generates morphograms from pairs of the received physiological signals; a signature generator (12) that applies a wavelet decomposition to each morphogram to compute a signature for each morphogram; and a decision component (14) that compares the morphogram signatures within and across sampling intervals and determines if a physiological change is a clinically significant change or an artifact.



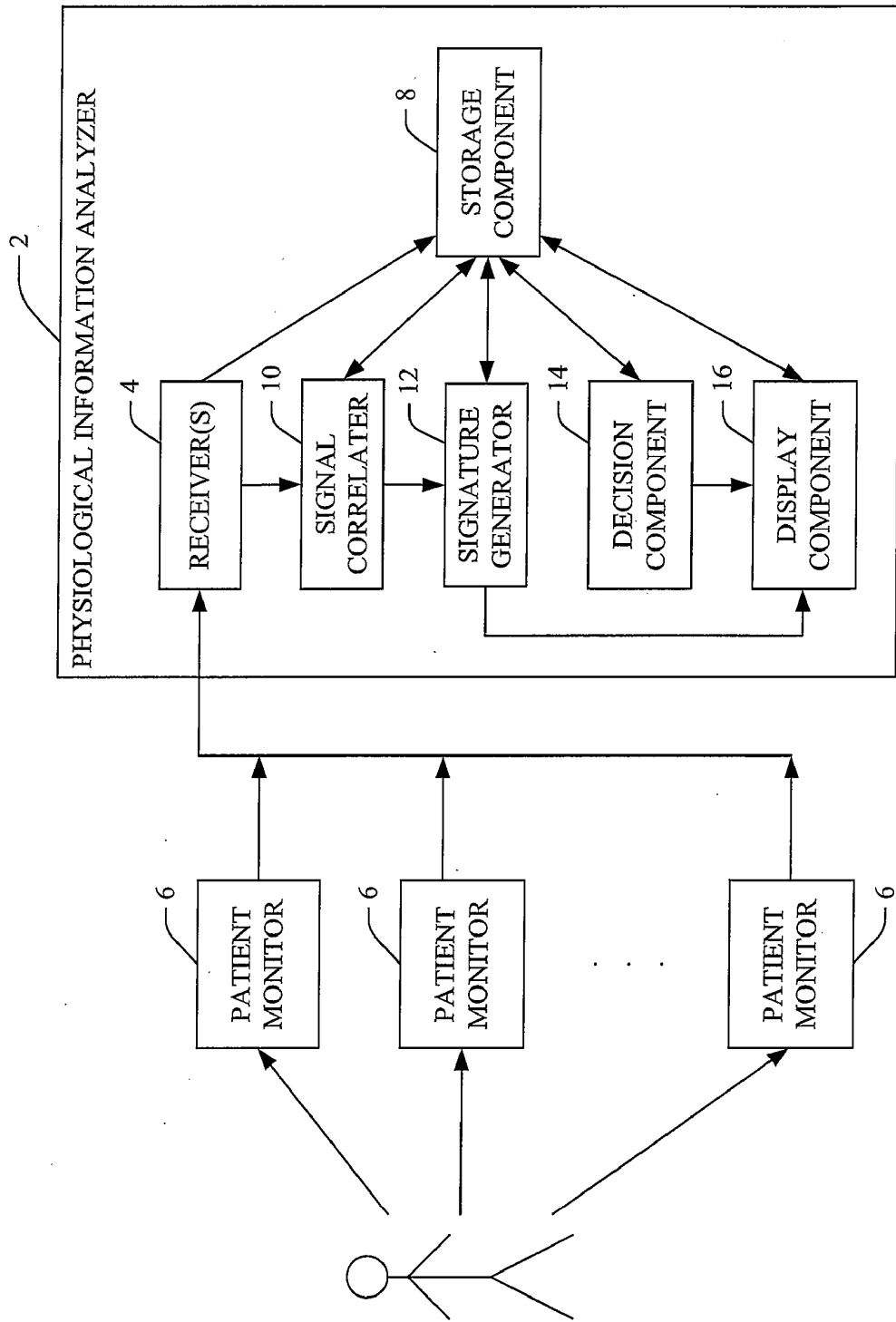


FIGURE 1

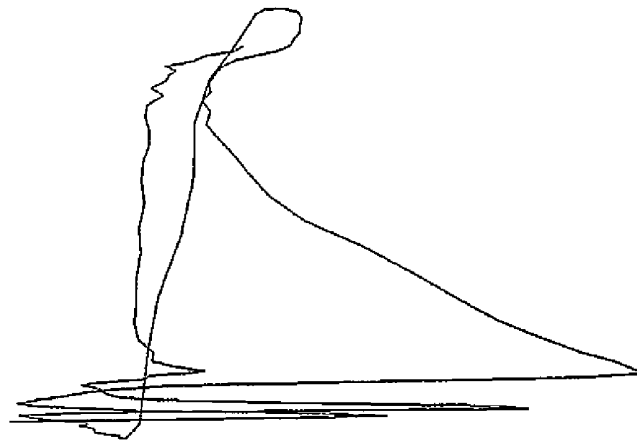


FIGURE 2

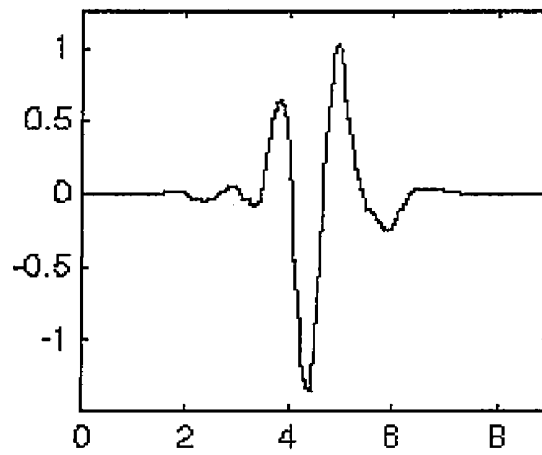


FIGURE 3

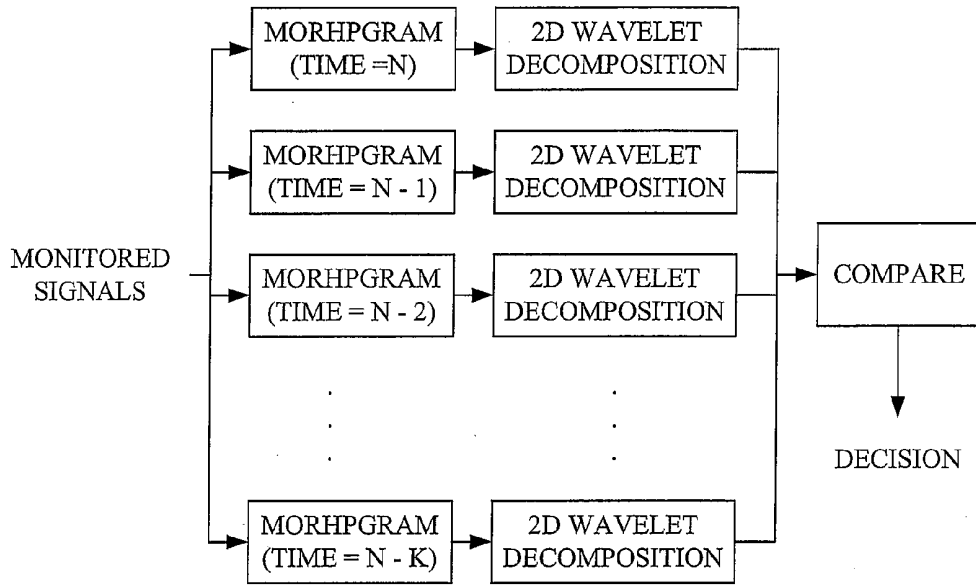


FIGURE 4

The interface displays the following components:

- Data (Size):** 300x1200
- Wavelet:** sym, Level: 5
- Level:** 2
- Buttons:** Analyze, Statistics, Compress, Histograms, De-noise
- Decomposition at level:** 2
- View mode:** Tree
- Full Size:** 1, 2, 3
- Operations on selected image:** Visualize, Full Size, Reconstruct
- Colormap:** gray
- Nb. Colors:** 2
- Brightness:** - +
- Close** button

The main window shows a grid of images for 'Image Selection : Decomposition at level 2':

- L₁ (20):** Original Image, Synthesized Image, and an empty box (22).
- L₂ (26):** Approximations (28), Horizontal Details (24), Diagonal Details (32), and Vertical Details (30).

At the bottom, there are navigation and utility buttons: X, Y, XY, Center On, Info, X-, Y-, History, and View Area.

FIGURE 5

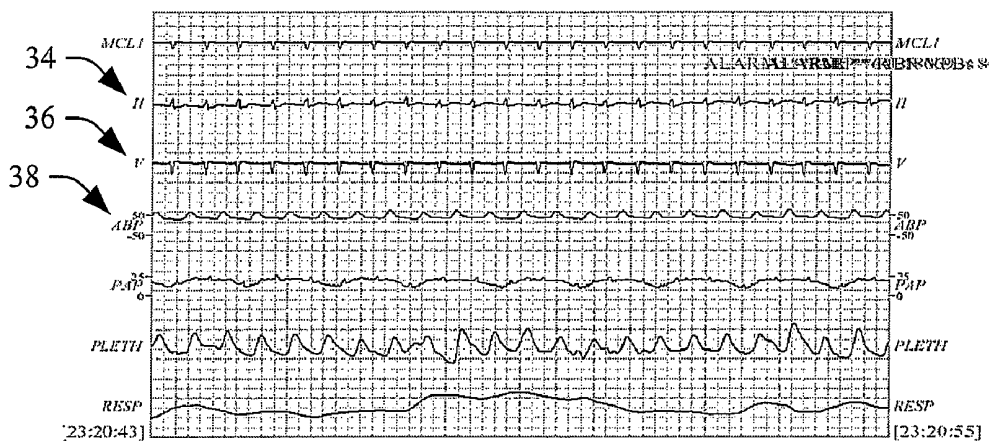


FIGURE 6

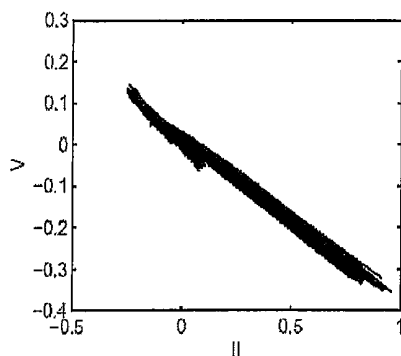


FIGURE 7

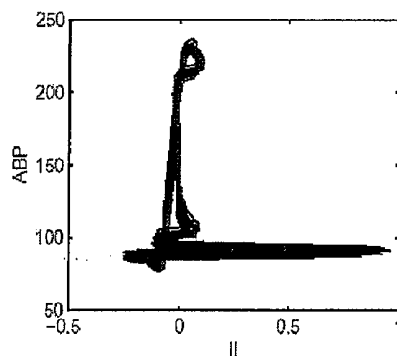


FIGURE 8

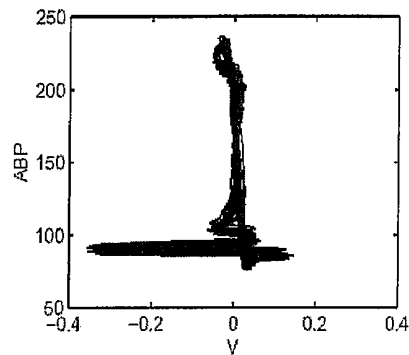


FIGURE 9

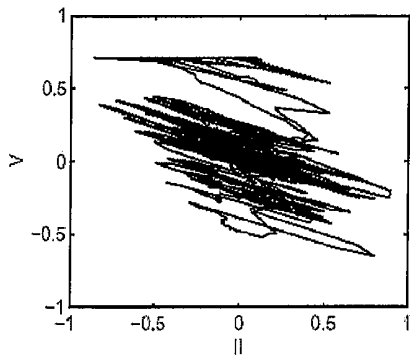


FIGURE 10

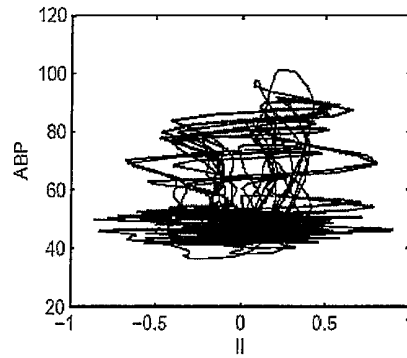


FIGURE 11

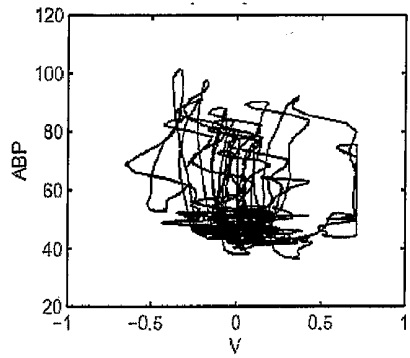


FIGURE 12

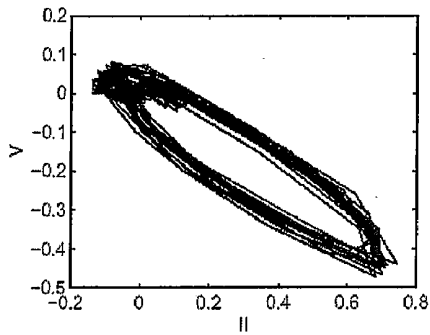


FIGURE 13

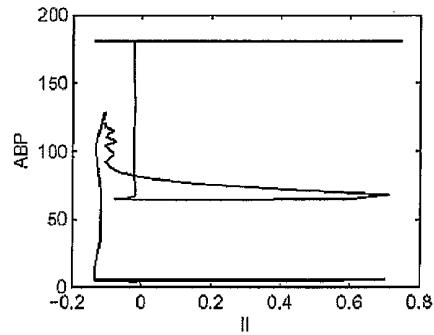


FIGURE 14

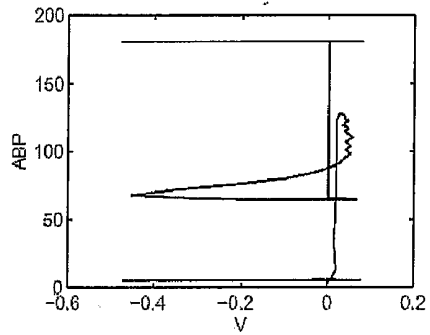


FIGURE 15

**METHOD AND APPARATUS FOR
DISTINGUISHING BETWEEN CLINICALLY
SIGNIFICANT CHANGES AND ARTIFACTS
IN PATIENT PHYSIOLOGICAL
INFORMATION**

[0001] The following relates to patient monitoring. It finds particular application to determining whether physiological changes captured by patient monitoring devices are clinically significant or artifacts.

[0002] Many intensive/critical care unit (ICU/CCU) patients have changing physiological conditions. Such patients are prone to deterioration and may periodically need immediate intervention when a clinically significant physiological change occurs. Thus, overall treatment is improved by close and accurate monitoring of physiological changes. Such monitoring is achieved through various patient monitoring devices. Of particular importance are physiological changes that invoke patient monitoring device alarms. When valid alarms are triggered, hospital staff (e.g., doctors, nurses . . .) begin evaluating and treating the patient. Many times, the evaluation results in concluding that the physiological change is not representative of a clinically significant change (e.g., a false alarm) or that no physiological change actually occurred (e.g., an artifact). Such alarms hinder clinical practice, obscure true critical events, and increase the amount of human intervention in intensive/critical care situations.

[0003] To mitigate attending to every false alarm, hospital staff learn to decipher between clearly erroneous alarms (e.g., by looking at the signal or value invoking the alarm) and alarms that potentially could be associated with a clinically significant physiological change. Thus, it is not uncommon for staff to ignore a sounding alarm. However, the staff is not always able to ascertain when a sounding false alarm obscures a later occurring critical event.

[0004] In one aspect, morphograms of physiological signals acquired by patient monitoring devices are decomposed via wavelet decomposition to generate unique signatures that are compared with each other to determine whether a physiological change is associated with a change in all related signatures (a clinically significant change) or whether the physiological change is only associated with a subset of signatures with a common signal (artifact).

[0005] In another aspect, a patient physiological information monitoring system includes a plurality of patient monitoring devices and a physiological information analyzer. The plurality of patient monitoring devices monitor physiological information from a patient and generate corresponding physiological signals. The physiological information analyzer processes the monitored physiological information and determines whether a physiological change is a clinically significant event or an artifact. The physiological information analyzer includes at least one receiver that receives the physiological signals from the patient monitoring devices; a signal correlator that generates morphograms from pairs of the received physiological signals; a signature generator that applies a wavelet decomposition to each morphogram to compute a signature for each morphogram; and a decision component that compares the morphogram signatures within and across sampling intervals and determines if a physiological change is a clinically significant change or an artifact.

[0006] One advantage includes determining whether a physiological change captured with a patient monitoring device is a clinically significant change or an artifact.

[0007] Another advantage resides in mitigating patient monitoring device false alarms.

[0008] Another advantage resides in reducing monitoring cost relative to other approaches that achieve a similar accuracy.

[0009] Another advantage lies in increased patient monitoring resolution.

[0010] Still further advantages will become apparent to those of ordinary skill in the art upon reading and understanding the detailed description of the preferred embodiments.

[0011] FIG. 1 illustrates a system that facilitates distinguishing between clinically significant changes and artifact in patient physiological information.

[0012] FIG. 2 illustrates an exemplary ECG-ABP morphogram.

[0013] FIG. 3 illustrates an exemplary Symlet wavelet.

[0014] FIG. 4 illustrates a routine for signature comparison over N-K sampling intervals.

[0015] FIG. 5 illustrates an exemplary graphical user interface for displaying signature coefficients.

[0016] FIG. 6 shows several plots of a typical set of physiological signals captured over time for a patient with respiratory failure.

[0017] FIGS. 7-9 illustrate three example morphograms generated from pairs from an ABP and two ECG signals.

[0018] FIGS. 10-12 show graphical examples of morphograms perturbed due to physiological changes in a patient's condition.

[0019] FIGS. 13-15 show graphical examples of morphograms perturbed due to an artifact.

[0020] FIG. 1 illustrates a patient physiological information monitoring system for alerting clinical staff when a physiological change captured by a patient monitoring device is a clinically significant change. The patient physiological information monitoring system includes a physiological information analyzer ("analyzer") 2 that analyzes monitored patient physiological information and renders a decision whether any particular perturbation in the physiological information is associated with a clinically significant physiological change.

[0021] The analyzer 2 includes one or more receivers 4 that receive patient physiological information indicative of a physiological state of a patient. Such physiological information is obtained from one or more patient monitoring devices 6 (e.g., a cardiac monitor, a hemodynamic monitor . . .) and/or directly from sensors (not shown) located on or proximate to the patient. By way of example, a patient with chest pain typically is monitored at a health care facility with an electrocardiograph (ECG) device that collects heart-related electrical signals from multiple ECG leads (e.g., 3 leads, 5 leads . . .) strategically positioned on the patient's body. The collected signals are processed and visually displayed (e.g., on paper or a monitor) for observance by a doctor or other medical staff. Such signals can be provided by the ECG device to one or more of the receivers 4 (e.g., through a wireless and/or wired connection). Using normally captured and processed physiological information (e.g., ECG signals) from the patient monitoring devices 6 enables seamless incorporation of the analyzer 2 into existing patient monitoring equipment without any need for software, hardware, or architectural changes to the patient monitoring equipment. Other monitoring devices monitor other physiological data, such as blood pressure, blood oxygen, respiration, and the like, and communicate the monitor inform the receivers 4.

[0022] Each of the receivers 4 is independently configured to collect physiological information from one or more of the patient monitoring devices 6. A receiver configured to collect physiological information from more than one of the patient monitoring devices 6 can collect such information concur-

rently through parallel channels or serially through a shared or one or more dedicated channel. Where more than one of the receivers **4** collects physiological information from more than one of the patient monitoring devices **6**, a subset of the receivers **4** may collect physiological information from the same monitoring device or a similar group of monitoring devices.

[0023] Each of the receivers **4** periodically collects physiological information during a sampling interval at a sampling rate (e.g. collect data for X seconds every Y seconds, where X and Y are positive real numbers and $X \leq Y$). The sampling interval and rate for any one receiver is based at least in part an alarm configuration of the patient monitoring device that is monitoring the physiological information, resolution, processing power and memory size of the analyzer **2**, and the discretion of the attending clinician. For instance, with a typical patient monitoring device, physiological conditions in the alarm range are monitored over a period of time (latency period) before a related alarm occurs in order to reach stability (e.g., and trigger an alarm with a high degree of correctness) and mitigate false alarms due to patient movement, erroneous signals, etc. For example, a series of anomalous blood pressure readings may be monitored for about a twelve second (e.g., the actual time is patient monitoring device/manufacturer dependent) period of analysis preceding invocation of a blood pressure alarm. If the blood pressure readings move out of the alarm range prior to lapse of the latency period, the blood pressure alarm is not triggered; but, if the blood pressure readings remain within the alarm condition range, the blood pressure alarm triggers upon lapse of the latency period.

[0024] The sampling rate of a particular receiver is a fraction of the latency period of the associated monitoring device so that the analyzer **2** may render a decision as to whether a significant physiological change has occurred prior to or when a patient monitoring device sounds an alarm. In another embodiment, the analyzer **2** sounds an alarm (e.g., its own alarm displays at a central monitoring station or it invokes a monitoring device to prematurely alarm) when it determines a clinically significant physiological change has occurred. Such alarm condition may be determined by the analyzer **2** well before the monitoring device latency period lapses, thereby reducing the time between a clinically significant physiological change and treatment thereof. In still another embodiment, the analyzer **2** can send a signal to the patient monitoring device to prevent or turn off an alarm when the analyzer **2** determines a physiological change is an artifact.

[0025] In the illustrated embodiment, the receivers **4** convey the physiological information to a signal correlater **10** for further processing or for storing the received physiological information in a storage medium **8** (e.g., RAM, cache . . .). The physiological information is conveyed/stored such that the data is separable based at least in part on monitoring device and sampling interval and time. Thus, physiological information associated with a particular monitoring device and/or collected during a particular sampling interval can be identified and retrieved. For example, physiological information from an ECG that was collected during a k th (where k is an integer greater than one) sampling interval can be identified from within all the physiological information collected over all the sampling intervals.

[0026] More specifically, the signal correlater **10** generates a morphogram for pairs of signals with physiological information captured during contemporaneous sampling intervals. Thus, if the physiological information includes information from N different monitoring devices, then the theoretical maximum number of morphograms generated for that sampling interval is

$$\sum_{i=1}^{N-1} X,$$

where X is the variable summed over. If data is collected for L (where L is an integer greater than one) sampling intervals, then the theoretical maximum number of morphograms at any given time is

$$L \sum_{i=1}^{N-1} X.$$

The actual number of morphograms generated and/or saved depends on factors such as a resolution and processing power, the size of storage medium **8**, and the monitoring clinician. The generated morphograms are conveyed to a signature generator **12** for further processing, displaying, or storage in the storage medium **8**.

[0027] Each morphogram is a mapping of one physiological signal against another. It illustrates how the two physiological signals move together. The ability of one type of physiological signal to follow another type of physiological signal depends on the correlation between the two types of physiological signals. In the patient monitoring domain, the morphogram depicts a relationship between physiological data such as an ECG signal and an arterial blood pressure (ABP) signal. This relationship can be mapped and visually presented using tools such as plot or graphs. For instance, the ECG data can be mapped to one axis and the ABP data can be mapped to another axis, such that the relationship is visually depicted through multi-dimensional graph. FIG. **2** illustrates an ECG-ABP morphogram, or characteristic signature, in which an ECG signal is mapped to a vertical axis and an ABP signal is mapped to a horizontal axis. This mapping between physiological signals can also be represented symbolically through an equation.

[0028] The signature generator **12** computes a signature for each morphogram in each of the sampling intervals and stores the signatures in the storage medium **8**. The signatures are stored based on patient monitoring device and sampling interval. For example, a signature for an ECG-ABP morphogram generated using ECG and ABP signals from an i th (where i is an integer greater than one) sampling interval can be identified from the other signatures. Because all physiological conditions do not have the same cycle periodicity, some morphograms may be based on different sampling intervals. The number of signatures stored at any given time is based at least in part on a size of the storage medium **8**, the computation power of the analyzer **2**, and the clinician monitoring the patient, for example.

[0029] The signature of each morphogram is a unique shape descriptor that represents morphogram shape characteristics such as inflection points, curvature, etc. Suitable transforms for generating shape descriptors include wavelet transforms and the like. In a preferred embodiment, the morphograms are processed with a two-dimensional (2D) wavelet transform (2D wavelet decomposition). FIG. **3** illustrates a Symlet wavelet, which is the preferable 2D wavelet to use with ECG and ABP based morphograms since they have similar shape characteristics. Of course, 3D wavelet transforms can be used where three signals are correlated, and so on for higher orders.

[0030] Two-dimensional wavelet decomposition of a morphogram renders a set of coefficients that describe each morphogram in a horizontal, a vertical, and a diagonal (which includes both horizontal and vertical components) detail. With highly correlated physiological signals, a set of three coefficients fully characterizes the 2D morphogram. More levels of detail can be employed, if desired or needed, to generate more coefficients and, potentially, more accurate analysis at the cost of computational resources. Typically, more levels of decomposition facilitate capturing shape variability for morphograms generated from less correlated signals. For instance, characterizing a sine wave with a square wavelet (low degree of correlation) generally requires more levels of decomposition than characterizing the sine wave with a sinc wavelet (higher degree of correlation).

[0031] A decision component **14** compares signatures (coefficients) within and across a set of sampling intervals. Such comparison detects perturbations in related signatures, which are indicative of physiological changes. For example, a physiological change in the heart can result in changes to either or both of ECG and ABP signals which result in changes to the morphograms and signatures generated therefrom. Upon using a signature to determine whether a physiological change is a clinically significant event or an artifact, the signature can be retained (e.g., for further use or as a historical record) or discarded (e.g., deleted, written over . . .).

[0032] The comparison is also used to determine whether a detected physiological change is a clinically significant physiological changes or artifact. It is to be appreciated that a change in the signature can be clinically significant even if neither monitor condition changes beyond its alarm threshold. In this way, clinically significant events may be detected early. The decision component **14** determines a physiological change is a clinically significant change base on the shape perturbation is in the signatures with signals related to the physiological change, and the decision component **14** determines a physiological change is an artifact if the shape perturbation is in a subset of signatures with at least one common signal. FIG. **4** shows an example in which signatures of morphograms generated over N-K sampling intervals are compared to render a decision.

[0033] A display component **16** visualizes the signatures for observance by the clinical staff. Such display can be at the bedside of the patient and/or at a remote monitoring station (e.g., a nurse station, over the Internet . . .). FIG. **5** illustrates an exemplary graphical user interface displaying coefficients for a two level, 2D Symlet wavelet decomposition of the ECG-ABP morphogram depicted in FIG. **2**. A first level of decomposition (L1) **18** includes a horizontal detail **20**, a vertical detail **22**, and a diagonal detail **24**, and a second level of decomposition (L2) **26** includes a horizontal detail **28**, a vertical detail **30**, and a diagonal detail **32**.

[0034] FIGS. **6-15** provide a particular example in which the analyzer **2** receives at least an ABP and two ECG signals from the patient monitoring devices **6**. FIG. **6** shows several plots of a typical set of physiological signals captured over time for a patient with respiratory failure. The set of signals includes an ECG lead II signal **34**, an ECG lead V signal **36**, and an ABP signal **38**.

[0035] The signal correlator **10** generates morphograms for at least the ECG lead II signal **30**, the ECG lead V signal **36**, and the ABP signal **38**. Examples of three morphograms generated from pairs of the signals **34-38** without changes or artifact are depicted in FIGS. **7-9**. In particular, FIG. **7** illustrates a morphogram generated from the ECG signal II/ECG signal V pair; FIG. **8** illustrates a morphogram generated from

the ECG signal II/ABP signal pair; and FIG. **9** shows a morphogram generated from the ECG signal V/ABP signal pair.

[0036] The morphograms in FIGS. **7-9** all have well-defined shapes that repeat with each as long as there are no artifacts and the patient is not undergoing physiological changes. Since ABP and the various ECG signals are highly correlated, the resulting morphogram represent characteristic morphology that represent the correlated signals for a single heart beat when the sampling rate is greater than one heart beat. In many instances, the ECG-ECG and ABP-ECG morphograms have characteristic shapes that can be generalized across patients.

[0037] Since the ABP wave lags behind the QRS complex, the ABP-ECG morphograms in FIGS. **8** and **9** have a characteristic "L" shape (or a backwards "L" shape). When the ABP is at a low value, the ECG approaches its maximum (or minimum). Similarly, when the ECG approaches a neutral value, the ABP approaches a maximum. This correlation between ABP and ECG signals accounts for the characteristic "L" shape. The pattern of the ECG-ECG morphogram in FIG. **7** lies along a diagonal typically about 45 degrees or 135 degrees (e.g., as a bar or an oval). This shape results since both signals reach extremes (e.g., some point in the QRS complex) in unison.

[0038] Morphograms showing significant departures from the signature are easily detected. Similarly, a morphogram that is changing over time (e.g., a gradual shorting along one leg of the "L") can be detected, and its rate of change can be clinically significant. These departures indicate either a physiologically change or an artifact. The underlying heuristic is that physiologically change is more likely to affect all signals, and thus there will be perturbations in all morphograms, whereas artifacts are more likely to affect only a single signal, and thus there will be perturbations only in the morphograms involving that signal. FIGS. **10-12** show graphical examples where the morphograms are perturbed due to physiological changes in the patient's condition. The changes in the patterns (relative to the patterns with no physiological changes or artifact shown in FIGS. **7-9**) are obvious in the morphograms generated from that signal; there are perturbations in each of the morphograms' morphology. FIGS. **13-15** shows a graphical example for a patient with pulmonary edema during a time period in which an artifact occurs in the ABP signal. As depicted, only the morphograms that include the ABP signal (FIGS. **14** and **15**, are perturbed; the morphogram in FIG. **13** for the two ECG signals retains its characteristic diagonal-oval shape; whereas, the two morphograms in FIGS. **14** and **15** with the ABP signal and either of the two ECG signals are highly distorted. Given that the signals in this example are highly correlated, the change in only the morphograms in FIGS. **14** and **15** indicate an artifact (e.g., a mechanical problem for that signal).

[0039] The signature generator **12** computes a signature or unique shape descriptor that characterizes the ECG-ECG and two ECG-ABP morphograms. As noted previously, in the preferred embodiment (and in this example) a 2D Symlet wavelet is used to generate morphogram signatures. The decision component **14** compares signatures (coefficients) within and across a predefined number of sampling intervals. Such comparison is used to detect physiological changes and determine whether they are clinically significant physiological changes or artifact. The decision component **14** determines a physiological change is a clinically significant change if the shape perturbation is in the signatures generated from signals related to the physiological change. Similarly, the decision component **14** determines a physiological change is an artifact if the shape perturbation is only in a subset of signatures

with at least one common signal and signatures of related signals from different monitors are not. One or more of the signatures are displayed in an interface for monitoring by the medical staff.

[0040] 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. 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.

1. A patient physiological information monitoring system, comprising:

- a plurality of patient monitoring devices that monitor physiological information from a patient and generate corresponding physiological signals; and
- a physiological information analyzer that processes the monitored physiological information and determines whether a physiological change is a clinically significant event or an artifact, the physiological information analyzer including:
 - at least one receiver that receives the physiological signals from the patient monitoring devices;
 - a signal correlator that generates morphograms from pairs of the received physiological signals;
 - a signature generator that applies a wavelet decomposition to each morphogram to compute a signature for each morphogram; and
 - a decision component that compares the morphogram signatures within and across sampling intervals and determines if a physiological change is a clinically significant change or an artifact.

2. The patient physiological information monitoring system as set forth in claim 1, wherein the decision component determines the physiological change is an artifact if the shape perturbation is only in a subset of signatures with at least one common signal.

3. The patient physiological information monitoring system as set forth in claim 1, wherein the decision component determines an alarm is valid if a shape perturbation is present in the signatures with signals related to the physiological change.

4. The patient physiological information monitoring system as set forth in claim 1, further including a display component that visually presents at least some of the signatures for observation by a clinical staff.

5. The patient physiological information monitoring system as set forth in claim 1, wherein the analyzer discards signatures that include artifact and stores signatures that include clinically significant physiological changes in a storage component (8).

6. The patient physiological information monitoring system as set forth in claim 1, wherein the wavelet is a Symlet wavelet.

7. The patient physiological information monitoring system as set forth in claim 1, wherein the signature of a morphogram is represented by one or more coefficients that fully describe morphogram shape variability.

8. The patient physiological information monitoring system as set forth in claim 7, wherein the one or more coefficients include a horizontal detail, a vertical detail, and a diagonal detail that includes both a horizontal component and vertical component.

9. The patient physiological information monitoring system as set forth in claim 1, wherein the wavelet decomposition includes one or more levels of decomposition.

10. The patient physiological information monitoring system as set forth in claim 1, wherein the sampling intervals occur at a sampling rate that is less than or equal to an alarm latency period of the corresponding patient monitor device, the alarm latency period corresponds to a time over which an alarm condition exists in order to trigger an alarm with a high degree of correctness.

11. The patient physiological information monitoring system as set forth in claim 1, wherein the physiological information includes at least one or more ECG signals and an arterial blood pressure (ABP) signal.

12. The patient physiological information monitoring system as set forth in claim 1, wherein the physiological information analyzer sounds an alarm and/or prematurely invokes a monitoring device to alarm when it determines a clinically significant physiological change has occurred.

13. The patient physiological information monitoring system as set forth in claim 1, the physiological information analyzer prevents or turns off a patient monitoring device alarm when the analyzer determines a monitored physiological change is an artifact.

14. A method for determining whether a physiological change captured by a patient monitoring device is a clinically significant change or an artifact, comprising:

- receiving physiological signals indicative of physiological information monitored from patient;
- generating a morphogram for pairs of the physiological signals as the physiological information for each sampling interval is received;
- applying a wavelet decomposition on each morphogram to generate a signature for each morphogram; and
- comparing the signatures within and across sampling intervals; and
- determining whether signatures perturbations are a result of clinically significant changes or artifacts.

15. The method as set forth in claim 1, wherein the wavelet is a Symlet wavelet.

16. The method as set forth in claim 1, wherein each signature is a unique descriptor represented as coefficients that describe morphogram shape variability.

17. The method as set forth in claim 15, further including using the result of the determination to invoke or override a patient monitoring device related alarm, the patient monitoring device alarm being invoked when the perturbation is determined to be due to a clinically significant physiological.

18. The method as set forth in claim 15, further including displaying at least the signatures for observation by clinical staff.

19. A computer programmed to perform the method of claim 14.

- 20. A method of patient monitoring, comprising:
 - generating morphograms from related patient monitoring signals;
 - decomposing the morphograms via a wavelet decomposition to generate signatures;
 - comparing changes in the signatures relative to each other or over time; and
 - based on the signature comparisons, determining whether a clinically significant event or an artifact has occurred.

* * * * *

专利名称(译)	用于区分患者生理信息中临床重大变化和伪影的方法和装置		
公开(公告)号	US20080208012A1	公开(公告)日	2008-08-28
申请号	US11/916767	申请日	2006-05-31
[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)	皇家飞利浦电子N. V.		
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外部链接	Espacenet	USPTO	

摘要(译)

患者生理信息监测系统包括多个患者监测装置 (6) 和生理信息分析仪 (2)。多个患者监测设备 (6) 监测来自患者的生理信息并产生相应的生理信号。生理信息分析器 (2) 处理所监测的生理信息并确定生理变化是临床重要事件还是人工制品。生理信息分析器包括至少一个接收器 (4)，其接收来自患者监测设备的生理信号;信号相关器 (10)，用于从接收的生理信号对中生成形态图;签名生成器 (12)，其将小波分解应用于每个形态描绘图以计算每个形态描绘图的签名;和决策组件 (14)，其比较采样间隔内和跨采样间隔的形态描绘特征，并确定生理变化是否是临床上显着的变化或伪影。

