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(54) Title: SYSTEM AND METHOD FOR AUTOMATIC CAPTURE AND ARCHIVE OF CLINICALLY MEANINGFUL VITALS

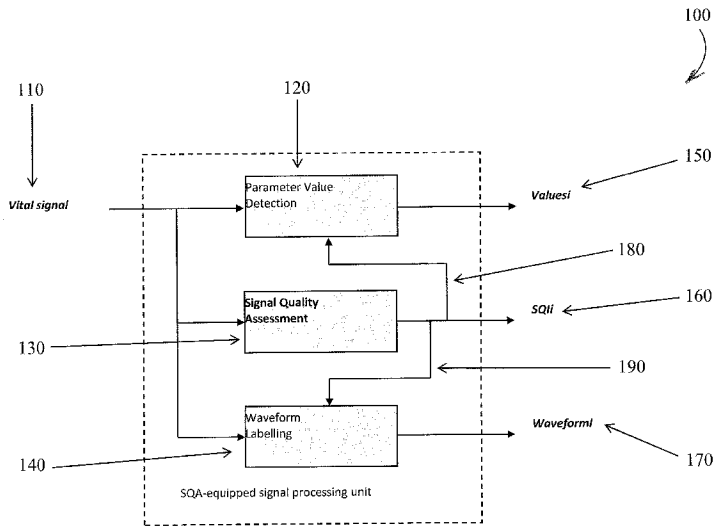

Fig. 1

(57) Abstract: Medical vital signs (110) are captured, recorded, processed, and a signal quality assessment (160) is computed based on signal waveform components such as slope, amplitude, time to rise, time at peak, and degree to which signal peaks (420) and valleys (430). The signal assessment (160) may be used as a basis for rating the quality (130) of the underlying vital signal, to increase the quality of the signal by removing noisy segments and physiologically impossible peaks (424) and valleys (434), to detect a parameter value (120), to label a waveform (140), or to prompt an alarm (550) to indicate the signal has reached a critical level and issue a warning to the user of the vital data. The signal and the assessment are stored in an indexed, searchable data storage memory (590) from which the signals may be retrieved and displayed (300).

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SYSTEM AND METHOD FOR AUTOMATIC CAPTURE AND ARCHIVE OF CLINICALLY MEANINGFUL VITALS

DESCRIPTION

The present application relates to the art of data collection and storage. It finds particular application to the collection of medical vital signs data and will be described with particular reference thereto. However, it will also find application in other types of displays.

Vital signs, or signs of life, include the following key objective clinical measurements: temperature, respiratory rate, heart rate, blood pressure and, where appropriate, blood oxygen saturation. These numbers provide critical vital information about a patient's state of health. All of these vital signs can be observed, measured, and monitored. Their measurement enables the assessment of the level at which an individual is functioning.

In particular, vital signs may indicate that a person is alive, identify the existence of an acute medical problem, be a means for rapidly quantifying the magnitude of an illness and how well the body is coping with the resultant physiologic stress, and may act as a marker of chronic disease states such as hypertension defined as chronically elevated blood pressure.

The benefits provided by automatic data collection of temperature, respiratory rate, heart rate, invasive/non-invasive blood pressure, or oxygen saturation from acute care monitoring devices have become so obvious that hospitals now require that their clinical information system (CIS), anesthesia information management system (AIMS), electronic medical records (EMR), electronic patient record system (EPR), or other hospital/healthcare information system (HIS) provide interfacing capabilities to biomedical devices in order to ensure that key vital signs are stored in the Centralized Data Repository (CDR) and to track patient progress over time.

While the importance of measuring, monitoring, observing and collecting clinical vital signs is not questioned, the accuracy and reliability of these measured vital signs may be questioned by medical practitioner users. A problem with vital signs manually collected from the acute care monitors, or from a nurse validated vital sign in CIS are that such vital signs are representative of the vital signs at that moment in time. Such

measurements are point abstractions which do not capture the most physiologically meaningful values such as peaks, valleys, and pathway travelled by that vital sign since it was last measured, monitored, observed and collected. Another problem with systems that try to capture the peaks and valleys is that they capture the highs and lows of the acute care monitor including the errors from signal noise and artifacts as well as signal dropouts. Filtering of this signal, or excluding extremes may reduce the errors, but does not remove such errors. Another problem with such results is that they do not produce a record of the extremes to validate the accuracy and reliability of such measurements. Because of such problems, the diagnosis or interpretation of the data becomes ambiguous or misleading, the alarm performance appears to be poor, and clinical inference engines or advisories frequently become ineffective. A further problem is that clinical users remain suspicious of automatically charted vital sign data because of the shortcomings of automated algorithms to distinguish noise from physiologic changes.

The present application presents a system that stores trended vital signs, and also produces associated waveforms in order to allow a user to interrogate the data to observe, recalculate, or verify a vital sign.

The present application introduces an automated signal quality assessment and control mechanism into patient monitoring CIS for automatic capturing vital sign values associated with good, clean physiological signals. Un-trustful or unreliable measurements associated with noise, artifacts and equipment problems are automatically detected and excluded from entering in the CIS inference engine for diagnosis and decision making purposes. Physiologically meaningful values and trends can be automatically captured, the vital alarm performance can be significantly improved, and the clinical inference engines/advisories can be much more effective and trustful.

The present application provides an improved system and method of capturing, storing, and graphically presenting vitals data. The present application is based on a new understanding and insight. It utilizes a new signal quality indicator from one or more physiologic waveform signals upon which the vital signs are derived to automatically capture accurate and reliable derived vital signs and associated raw waveform snippets that are representative clinical meaningful attributes of clinical data.

In accordance with one aspect, a signal processing system is presented which is comprised of at least one Signal Quality Assessment (SQA)–equipped processing unit; an information processor; a searchable data storage medium; and a selectable data display medium.

In accordance with one aspect, a signal quality assessment and control system is presented for capturing and archiving physiologically meaningful monitored data comprising a parameter value detection processing unit which receives raw physiological parameter signals (in which there may be untrustful or unreliable portions) and generates physiologically meaningful and reliable parameter data, a signal quality assessment processing unit which receives the physiological signals, accesses quality of the physiological signals, and generates signal quality indices indicative of the assessed quality of the physiological signals, and a waveform labeling unit which associates the signal quality indices with the physiological waveform data.

In accordance with one aspect, a method is presented for capturing and archiving a signal quality assessment and control by creating a signal quality indicator comprising the steps of capturing the peak, the valley, and the raw signal of physiological parameter signals, generating physiological parameter data through a parameter value detection processing unit to provide auto-charted data to the electronic record, by sampling and saving occasional waveform snippets, sampling and saving featured vectors, and compressing the waveform snippets and vector features to record patient encounter recovery, receiving physiological parameter signals, accesses quality of the physiological parameter signals, and generates a signal quality index indicative of the assessed quality of the physiological parameter signal through a signal quality assessment processing unit, and associating the signal quality indices with the physiological parameter data at a waveform labeling unit and archiving the patient encounter history in a computer operable database.

In accordance with one aspect, a method is presented of compressing the medical vital sign history of a patient encounter is presented which is comprised of receiving a vital sign; creating a signal quality indicator (SQI), capturing peak, valley, and vitals of a vital sign through using the SQI, producing a high-quality vital sign by removing the physiologically impossible or technically untrustful peaks and valleys from the vital signal, storing a the high quality vital sign, and displaying the high-quality vital sign.

In accordance with one aspect, a signal processing system is presented which comprises at least one SQA-equipped processing unit comprising a parametric value detection component, a signal quality assessment component, and a waveform label component; an Information Central Station (ICS) processor comprising a data-capture control (DCC), a system-level alarm manager, a clinical decision support (CDS) engine/clinical advisory, an event-evidence review control, a computer operable data storage memory containing an indexed searchable data set; and a selectable data display medium consisting of at least one of a computer display monitor, a waveform monitor, and an LED display.

An advantage resides in the creation of an SQI for a vital sign reflective of the accuracy and reliability of the measurement at that moment in time.

A further advantage is the utilization of the SQI's to improve quality and reliability of vital trends.

Another advantage is utilization of the SQI's to capture peak and valley of vitals along with associated raw signal snippets that do not include faulty extremes caused by noise and signal dropouts.

A still further advantage resides in an automatic capture of physiologically meaningful peaks, valleys, and typical vitals.

An advantage resides in a method to provide high quality "auto-charted" data to the Electronic Medical Record (EMR).

A still further advantage resides in a method to automatically reduce or compress the history of the patient encounter.

The present application would be useful to all clinicians in all areas of the hospital, from the lowest acuity to the highest acuity patients. Another use would be for the higher acuity patients that are having multiple measurements performed at the same time. It would be useful at the point of care as well as central and remote. Thus, it would find application on all bedside monitors as well as central stations, clinical information systems and/or hospital information systems.

The present application 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 present application.

Figure 1 is a diagrammatic illustration of a SQA-equipped vital-sign signal processing unit.

Figure 2 is a diagrammatic illustration of an arterial blood pressure (ABP) signal quality assessment component.

Figure 3 presents an example of an ABP signal quality index.

Figure 4A presents an example of ABP readings over 40 hours without SQA and control.

Figure 4B presents an example of ABP readings with SQA and control.

Figure 5 illustrates the ICS processor layout.

Figure 6 illustrates a sample display.

Figure 7 illustrates a method flowchart.

With reference to Figure 1, in an automated SQA and control signal processing unit 100, a vital signal 110 is presented to a plurality of vital-sign signal processing units 120, 130, 140. A signal quality assessment processing unit (SQA) 130 assesses the incoming vital signal 110 for each of a plurality of episodes, such as beat-by-beat for cardiovascular signals, breath-by-breath for respiration, an appropriate time interval for temperature measurements, etc. The SQA components 130 generates a signal quality measure index (SQI_i) signal 160 for each episode, at each beat or cardiac cycle, for example, and indicates the quality of the signal corresponding to each episode. The SQI_i is also passed 180, 190 to the other signal processing units 120, 140.

The SQI_i signals 160 are utilized by a parameter value detection (PVD) process in unit 120. The PVD processing unit 120 detects the vital sign parameter 110 values from the signal episodes that are rated as having good signal quality according to the SQI_i and removes or replaces those rated as having poor signal quality according to the SQI_i. When no good SQI values (160) occur for an established period of time, the information control processor (510) indicates the SQI value (160) as bad and the vital value as questionable. A waveform labeling unit 140 attaches the SQI_i to the signal waveform

110 to create an SQA-labeled waveform 170. In this manner, each episode of the waveform is labeled with a corresponding signal quality index value 160. Due to the signal processing unit 100, the reliability of the vital signal, e.g. free from noise and artifacts, is indicated by SQI_i. The resulting vital sign values are much more physiologically meaningful. The signal quality index value (SQI_i) signal 160, parameter values measured with SQI control ($Values_i$) 150, and SQI_i labelled waveforms ($Waveform_l$) 170 are all available to the patient monitoring system or CIS. The true patterns of the vital sign changes are readily retrievable. Furthermore, since only the "true and meaningful" data are stored through this application and unnecessary data is not stored, fewer electronic, computer memory, database facilities, and hard copy resources are needed to store or represent the data related to the patient's visit to a medical facility

With reference to Figure 2, an example of implementing such a SQA component for an arterial blood pressure (ABP) signal 220 is presented. The ABP SQA component 130 includes an ABP waveform feature extraction (WFE) unit 230 and waveform feature analysis (WFA) unit 240 which produces the SQI_i signal 160.

In the WFE process 230, a set of ABP waveform features are extracted on an episode by episode, e.g. beat by beat, basis. Those features are predefined to be sensitive for distinguishing between ABP signal 220 and artifacts. Such features may include amplitudes, which is the height of the peak of the signal above the center of the waveform or the depth of the valley of the signal below the center of the waveform. Features may also include slopes of how fast the peak rises above the center or how fast the valley falls below the center of the waveform. Features may also include a length of specific time intervals, such as how long the signal remains at a peak or a valley value. In the WFA unit 240, linguistic or fuzzy variables such as *'ABP_amplitude_is_too_large'*, *'ABP_keeps_rising_too_long'*, and *'ABP_slope_is_too_small'* are employed to represent the waveform feature patterns, and a fuzzy logic reasoning approach is utilized to derive a signal quality index from inference of the linguistic variables.

An example of a fuzzy variable called *'ABP_signal_quality_is_good'* is set forth below:

IF [*'ABP_amplitude_is_normal' (AN)*] **AND**
[*'ABP_slope_is_normal' (SN)*] **AND**
[**NOT** *'ABP_keeps_rising_too_long' (KRTL)*] **AND**

[**NOT** *'ABP_stays_high_too_long' (SHTL)*] **AND**
[**NOT** *'ABP_with_blooked_transducer' (WBT)*]

THEN *'ABP_signal_quality_is_good' (SQG)*

$$SQI_i = \mu_{SQG} = \mu_{AN} \wedge \mu_{SN} \wedge (1 - \mu_{KRTL}) \wedge (1 - \mu_{SHTL}) \wedge (1 - \mu_{WBT})$$

The signal quality index (SQI_i,) 160 is defined as the value of the membership function of *'ABP_signal_quality_is_good'*. As the WFE unit 230 and the WFA unit 240 processes proceed, an SQI_i time series is generated which are corresponding to each beat cycle. Each of the SQI_i has a value between zero, with 0 indicating the worst signal quality, to one with 1 indicating the best signal quality.

With reference to Figure 3, an example of ABP signal quality index 160 is presented. A readout display 300 illustrates a trace resulting from above ABP SQA process. A top trace 310 represents an electrocardiogram (ECG) signal, a second trace 320 represents the ABP signal 220 with artifacts, and a bottom trace 330 represents the SQI_i time series 160 generated by the ABP SQA unit 240 (Please note, in Fig. 3, the SQI_i signal lags ABP by one beat interval). As illustrated, the SQI_i indicates when the ABP signal quality is reliable and when it is artifacted or otherwise unreliable.

The system also enables the user of such a system to adjust the "tolerance" of an SQI to allow saving/capturing data at a desired data rate as well as signal quality. For example, if a user wants to store data at 5 minute resolution, the SQI can be adjusted accordingly to allow such a resolution of data to be stored.

With reference to Figure 4A, the effect of signal quality assessment is presented. The ABP value can be selectively measured from the durations when the SQI_i, signal 170 indicates a reliable blood pressure measurement episode. A systolic ABP 410 without the signal quality assessment and control is shown in Fig. 4A and systolic ABP 440 measured from the same patient incorporating the signal quality control is shown in Fig. 4B.

In Figure 4A, without signal quality assessment and control 410, the blood pressure signal 220 is plotted as a graph with time on an x-axis 412 and systolic ABP on a y-axis 414. The waveform is centered 415 around a value of 100 with extreme peaks 424, and double peaks 426, and lesser peaks 420, 422. The waveform also contains extreme

valleys 434, and double valleys 436, along with less varying, lesser valleys 430, 432. The extreme peaks 424, 426 and extreme valleys 434, 436 may be caused by noise or signal distortion that may over ride and overwhelm the true peaks 420, 422 and the true valleys 430, 432 of the waveform.

In Figure 4B after the application of signal quality assessment and control 440, the waveform is illustrated as a graph with an x-axis 442 and systolic ABP on a y-axis 444. The waveform is still centered 445 around the same value of 100 in this case, but the extreme peaks and valleys have been removed, leaving the more moderate peaks 450, 452, and moderate valleys 460, 462 remaining to indicate an artifact free clearer signal from which a trend of the blood pressure over time can be readily assured.

The charts demonstrate that processing the waveform signal by application of the signal quality assessment and control 100 produces a chart that contains much more physiologically meaningful ABP trend data especially, in terms of peaks and valleys than does the not processed waveform 410. The SQI_i are attached to the signal on a beat-by-beat manner. So that by searching on SQI_i, it is easy to find where the signal is good and where is not. The reliability of alarms based on the vital sign values measured with signal quality control are therefore significantly improved.

With reference to Figure 5, a patient monitoring Information Central Station (ICS) 500 incorporates the SQA-equipped Processing and control units 100 of Figure 1. Although this processing is being described as being within the ICS, it could equally well be located within any device on the hospital network, including the bedside monitor. The ICS processor receives the outputs 150, 160, 170 from one, or a plurality of the SQA-equipped vital sign processing units (SQAe-PUs) 520, 522, 524. If a SQAe-PU is not available in the front-end device, then the raw vital signals (VS_i) 110 or a plurality of raw vital signals 530, 532, 534, may be received by the corresponding SQAe-PU functions at the ICS environment. An ICS processor 510 has the following processing components: data-capture control (DCC) 540; system-level alarm manager unit 550; a clinical decision support (CDS) engine or clinical advisory unit 560, and an event-evidence review control unit 570.

The DCC unit 540 determines how to capture the physiological meaningful vital sign values. For each vital sign channel, in a scheduled time interval such as 30 minutes, the DCC checks the SQI_i value generated from the corresponding SQAe-PU at the

scheduled times. If the SQI_i value is sufficiently high, the value is captured. However, if the SQI_i is poor at the scheduled time, then the value is not captured, and instead, the most recent value with good SQI_i is located and captured. This is referred to as retrospectively correcting the data. Furthermore, the peaks 450, 452 and the valleys 460, 462 of the value with good SQI_i are also captured. The data may include such matter 599 as physiologically meaningful values 575 as: trends, events, alerts, alarms, waveforms, and the like. A duration and sampling time of each waveform snippet that is stored can be a function of a use model. For example, for auto-charting data at one numeric sample per hour, 10 seconds or more of waveform data can be stored as part of the electronic medical record if the signal quality is deemed to be adequate. The user may also adjust the frequency and length that waveform data is stored based upon storage requirements or the like.

The system stores the captured vital sign data values and the corresponding SQI_i and SQI_i labeled waveforms 580 in an indexed searchable storage database 590 of patient records. The data is stored in a data warehouse arrangement to facilitate data analysis, such as cross correlation analysis, data mining for pattern detection within the accumulated data, projection and probability analysis in order to implement and operate a clinical decision support engine, and the like. The data and the data analysis components may produce output that may be displayed 585 in the readout display 300, such as but not limited to an LCD display, a cathode ray tube terminal, a waveform monitor, an LED display, and the like.

The system-level alarm manager 550 receives the captured vital sign values from above the described DCC unit 540, and performs validations of alarms that are issued from front-end devices or generates new alarms according to the alarm-criteria, as defined in the ICS, and/or based on the cross-correlations between different vital signs. Because the values that trigger the alarm are derived from clean signals, with good quality, the alarm performance is significantly improved. The validated and/or newly-generated alarms are also stored in the searchable storage 590 database and can be issued via an alarm interface 599.

The CDS engine/clinical advisory 560 receives the captured vital sign values from above DCC process unit, and performs various CDS applications which generate comprehensive clinical alerts and/or advisories about the patient state. As the input data values are more reliable than those from traditional manner, without signal

quality control, the effectiveness of the CDS applications is significantly enhanced. The clinical alerts and/or advisories generated are also stored in the searchable storage database 590.

The event-evidence review control unit 570 provides comprehensive graphic user interface to the end users such as clinicians. It displays, in arbitrary scales, the captured vital sign and accompanying SQI_i values, trends, the corresponding SQI_i labeled waveforms and the like. The alarms/alerts are visualized and reviewed with underneath evidence at a desired scale and manner in a graphic image, text table, and the like. It also provides comprehensive search capability that allows clinicians to efficiently locate points of interests and/or specific statistics.

With reference to Figure 6, the display 300, illustrates vital sign parameters 610 and their values at different time points 620, vital sign graphical trends 630, events 640, and associated captured waveform snippets 650. A user interface allows a clinician to rapidly review the high quality auto charted data to observe key events that may have been missed when they actually occurred. The interface may also be viewable across a computer operable network such as, but not limited to, a LAN, a WAN, and the Internet. The use of a network may also allow practitioners from remote locations to read, interact with, and adjust the readings displayed by the present application.

One utility of the present application is to provide high quality auto charted electronic medical records thus removing the need for user validation of data and providing improved accuracy. The SQI_i is attached to the signal on an episode basis so that by searching on SQI_i, it is easy to find where the signal is good. The accuracy of alarms based on the vital sign values measured with signal quality control is therefore significantly improved.

With reference to Figure 7, the steps of the method 700 are presented. In a first step 710, a signal quality indicator is created. In a peak capture step 720 true physiological peaks of vital signals are captured by utilizing the signal quality indicator. In a valley capturing step 730; true physiological valleys in vital signals are captured by utilizing the signal quality indicator. In a raw signal capturing step 740, a raw signal absent noisy peaks and noisy valleys and noisy signals is created. An auto-charted data step 750 provides physiologically meaningful, reliable auto-charted data to the electronic

medical record searchable storage database 590. A snippet step 760 samples and saves physiologically meaningful, reliable waveform snippets periodically. A featured vector step 770 samples and saves physiologically meaningful, reliable feature vectors. A compressing step 780 compresses waveform snippets and vector features for recording in a patient encounter history. A quality step 790 addresses and saves signal quality indicators. An archiving step 795 archives patient encounter history. The method may also display the archived data.

The present application 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.

CLAIMS:

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

1. A signal quality assessment and control system (100) for capturing and archiving monitored physiological data, the system comprising:

a parameter value detection processing unit (120) which receives physiological parameter signals and generates physiologically meaningful and reliable parameter data;

a signal quality assessment processing unit (130) which receives the physiological signals, accesses quality of the physiological signals, and generates signal quality indices indicative of the assessed quality of the physiological signals; and

a waveform labeling unit (140) which associates the signal quality indices with the physiological data.

2. The systems according to claim 1, wherein the signal quality assessment processing unit (130) includes:

a waveform feature extraction unit (230) which extracts episodes from the parameter signals.

3. The system according to claim 2, wherein the signal quality assessment processing unit (130) includes:

a waveform feature analysis unit (240), which compares each episode with preselected characteristics.

4. The system according to claim 3, wherein the waveform feature analysis unit (240) determines whether each episode meets preselected criteria and further including at least one of:

a memory (590) which stores the physiological parameter data of the episodes which meet the preselected criteria; and

a display (300) which displays the physiological parameter data of the episodes which meet the preselected criteria.

5. The system according to claim 3 wherein the waveform feature analysis unit (240) determines a signal quality index (SQI) and further including at least one of:

a display (300) which concurrently displays the physiological parameter data of each episode and its signal quality index;

a memory (590) which stores the physiological parameters data of each episode in association with its signal quality index; and

a tolerance which allows capturing data at a desired rate.

6. The system according to claim 3, wherein the preselected characteristics include signal amplitude and rate of signal amplitude change.

7. The system according to claim 3, wherein the physiological parameter signals include an EKG signal and each episode corresponding to a heartbeat.

8. A patient monitoring station (500) comprising:

a plurality of the signal quality and assessment systems (100) according to claim 1;

an information control processor (510) which receives the physiological parameter data and the signal quality signals from the systems (100) and as least one of archives in a memory (590) or displays on a display (300) physiological parameter and signal quality information, or triggers an alarm (599).

9. The system according to claim 8, wherein the information control processor (510) contains a data-capture control (DCC) (540) which determines if the SQI value is good and if the SQI value (160) is good, then the DCC (540) stores the vital value at that point in time, else the DCC (540) stores the most recent vital to represent that point in time.

10. The system according to claim 9, wherein the information control processor (510) leaves the SQI value (160) as bad and vital value as questionable when there are no good SQI values (160) for an established period of time.

11. The system according to claim 8, wherein the information control processor (ICP) (510) contains at least one of:

a system-level alarm manager (550) which generates an alarm based on at least one of alarm defined criteria and on alarm criteria based on the cross correlation between different vital signs;

a clinical decision support (CDS) engine/clinical advisory (560) which includes at least one of a clinical alert and advisory about the patient's state is generated from vital sign values received from the DCC; and

an event-evidence review (570) which controls at least one of captured vital sign values, SQI values, trends, and corresponding SQI labeled waveforms displayed using arbitrary scales.

12. A signal quality assessment and control method for capturing and archiving monitored physiological data, the method comprising:

generating physiologically meaningful and reliable parameter data from received physiological parameter signals;

assessing a quality of the physiological parameter signals and generating signal quality indices indicative of the assessed quality of the physiological parameter signal; and

associating each signal quality index with corresponding physiological parameter data.

13. The method according to claim 12, further including extracting episodes from the parameter signals.

14. The method according to claim 13, further including comparing each episode with preselected characteristics.

15. The method according to claim 14, further including:

determining whether each episode meets preselected criteria;

storing the physiological parameter data of the episodes which meet the preselected criteria; and

displaying the physiological parameter data of the episodes which meet the preselected criteria.

16. The method according to claim 14, wherein the preselected characteristics include a signal amplitude and a rate of signal change.

17. The method according to claim 14, wherein the physiological parameter signals include a blood pressure signal and each episode corresponds to an interval between blood pressure measurements.

18. The method according to claim 14, further including:

assessing a quality of physiological parameter signals corresponding to a plurality of physiological parameters of a patient; and

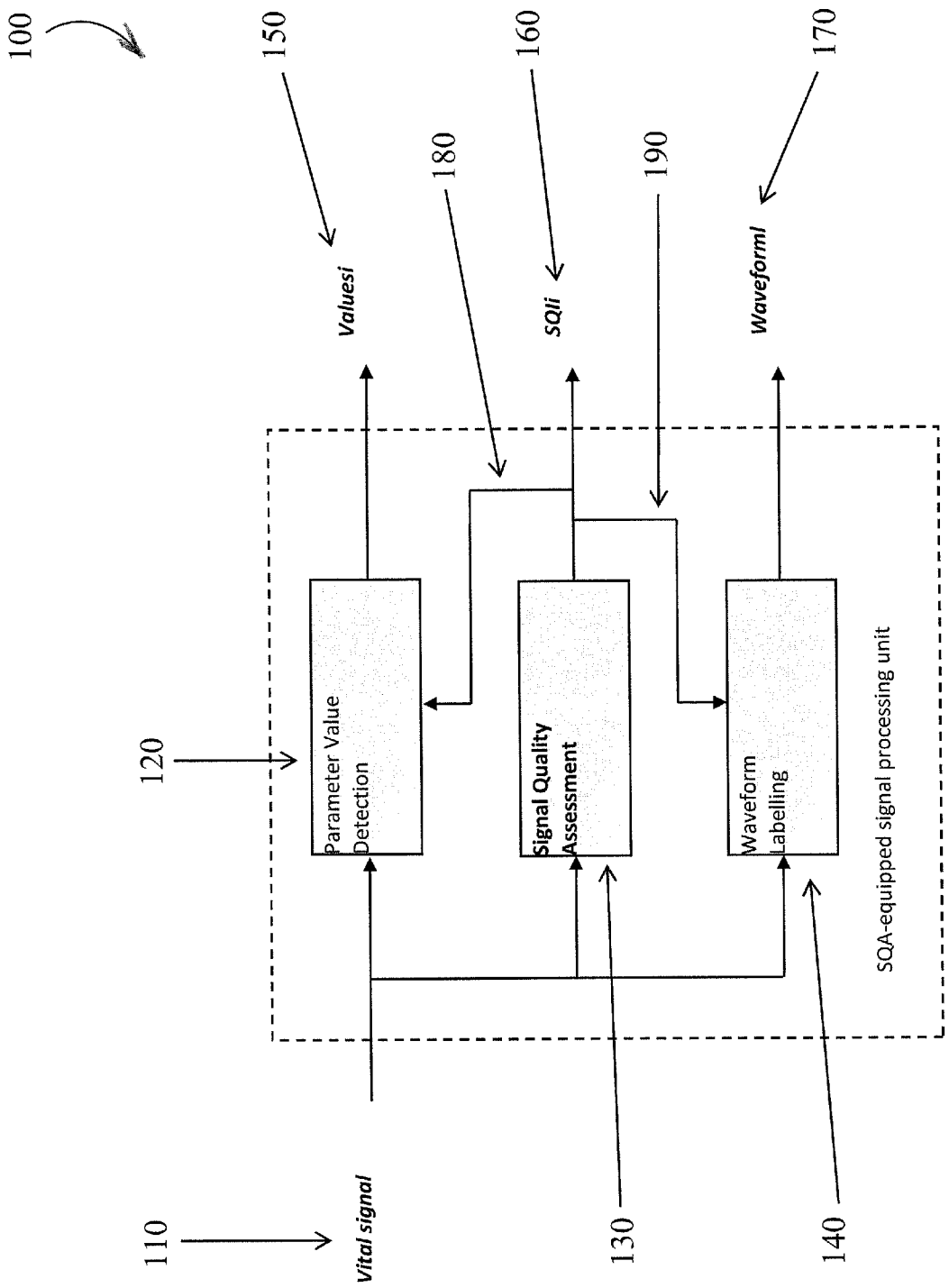
displaying the physiological parameter signals and the corresponding signal quality index for each of the physiological parameter signals on a common display.

19. The method according to claim 14, further including:

generating an alarm based on a defined alarm criteria based on a cross-correlation between the physiological parameter signals.

20. The method according to claim 14, further including:

reducing hardware computer memory storage resources to save and store the physiologically meaningful parameter data through removal of meaningless or unreliable data.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110
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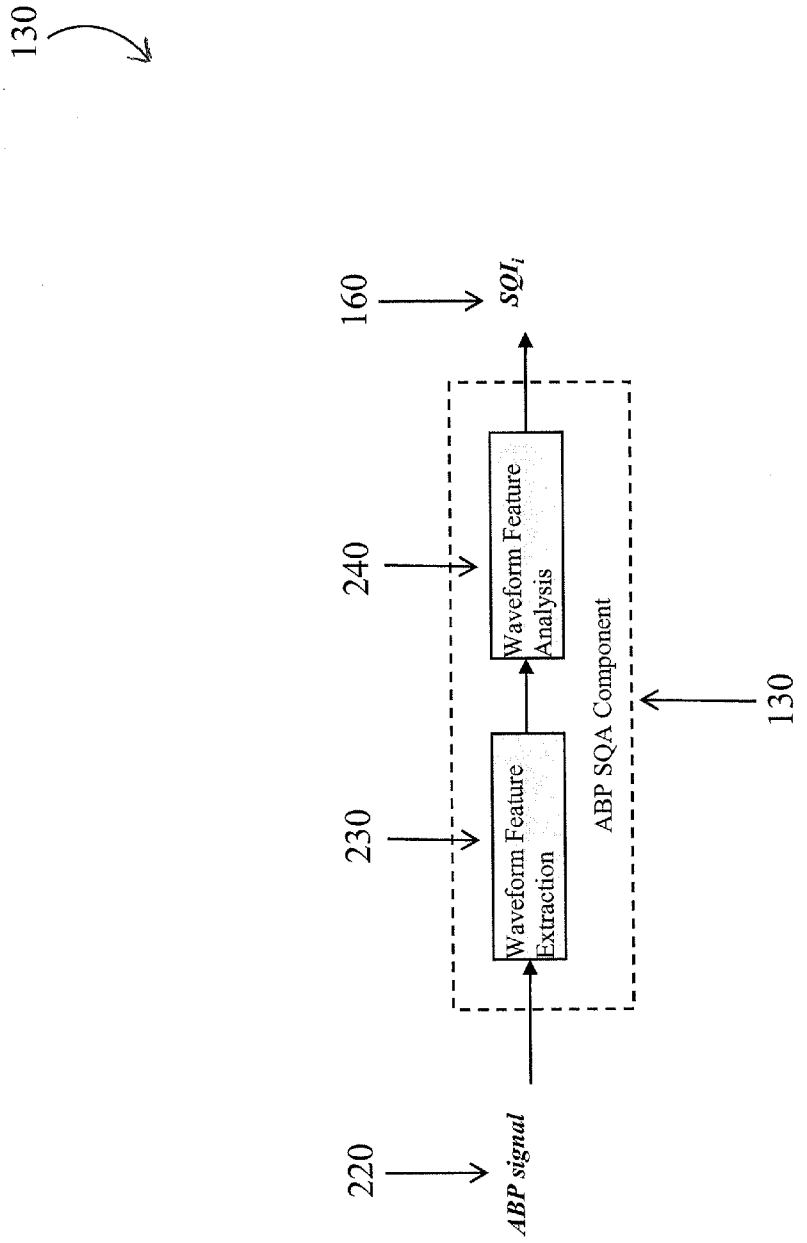
Fig. 1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160
SQI_i
240
Waveform Feature Analysis
230
Waveform Feature Extraction
ABP SQA Component
130
220
ABP signal

Fig. 2

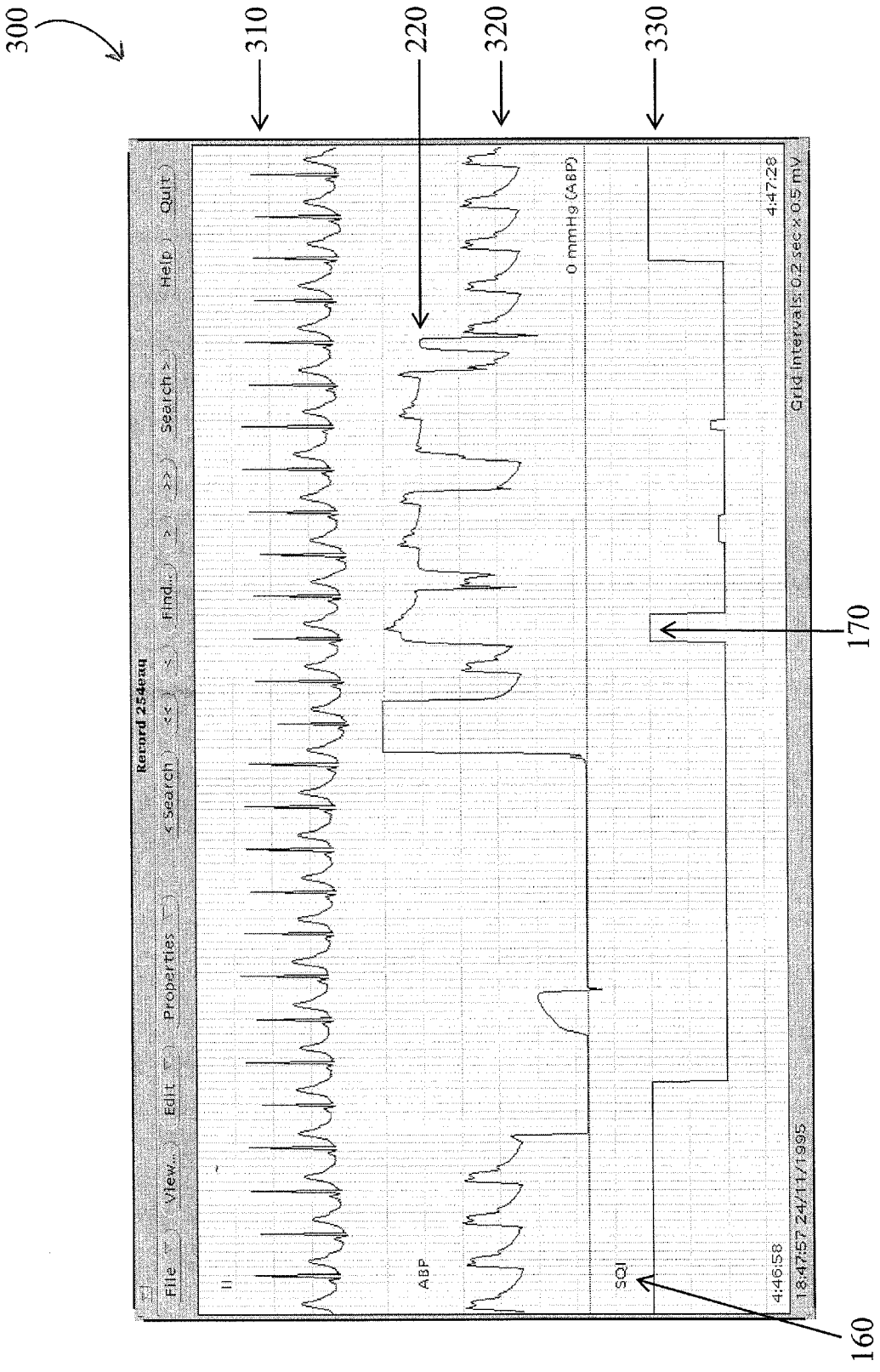
300
310
220
320
330
170
160
Record 254eaq
File
View...
Edit
Properties
< Search
<<
<
Find...
>
>>
Search >
Help
Quit
II
ABP
0 mmHg (ABP)
SQI
4:47:28
Grid Intervals: 0.2 sec x 0.5 mV
4:46:58
18:47:57 24/11/1995

Fig. 3

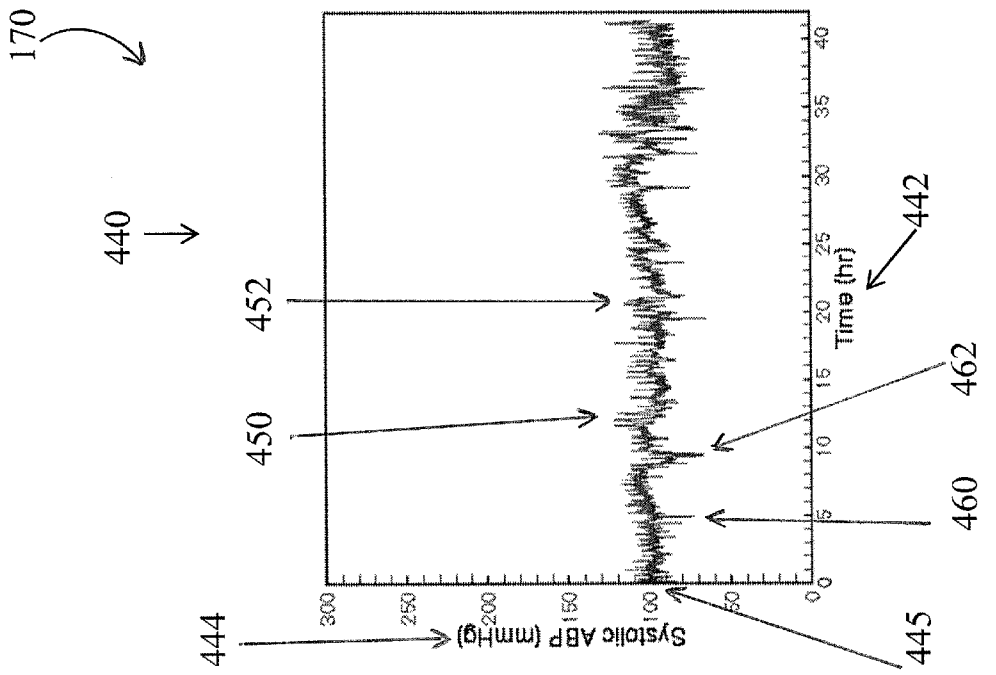
170
440
452
450
442
462
460
444
445
Systolic ABP (mmHg)
Time (hr)

Fig. 4B

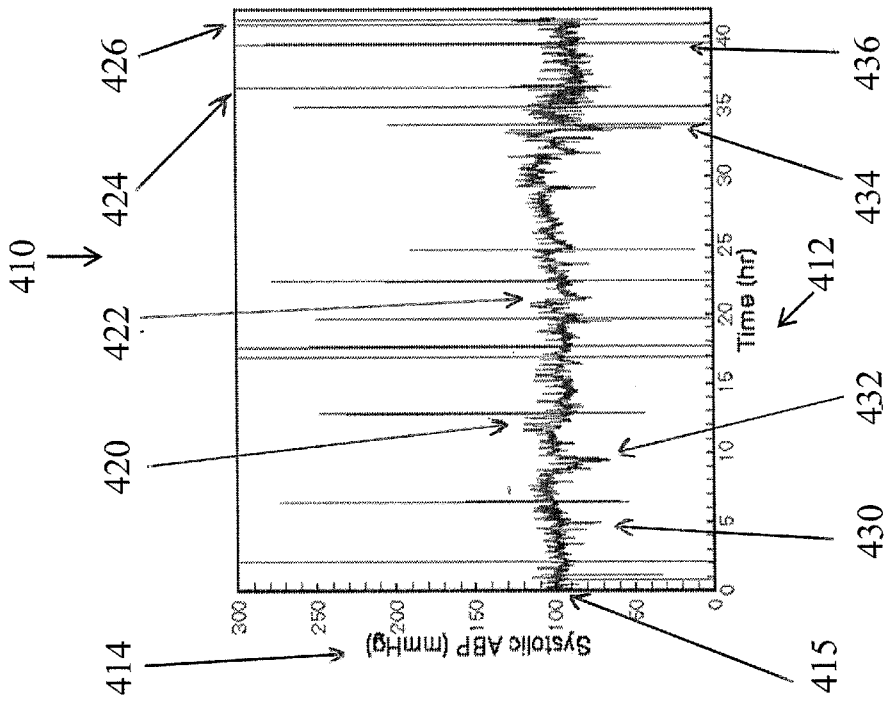
410
426
424
422
420
414
436
434
432
430
415
412
Systolic ABP (mmHg)
Time (hr)

Fig. 4A

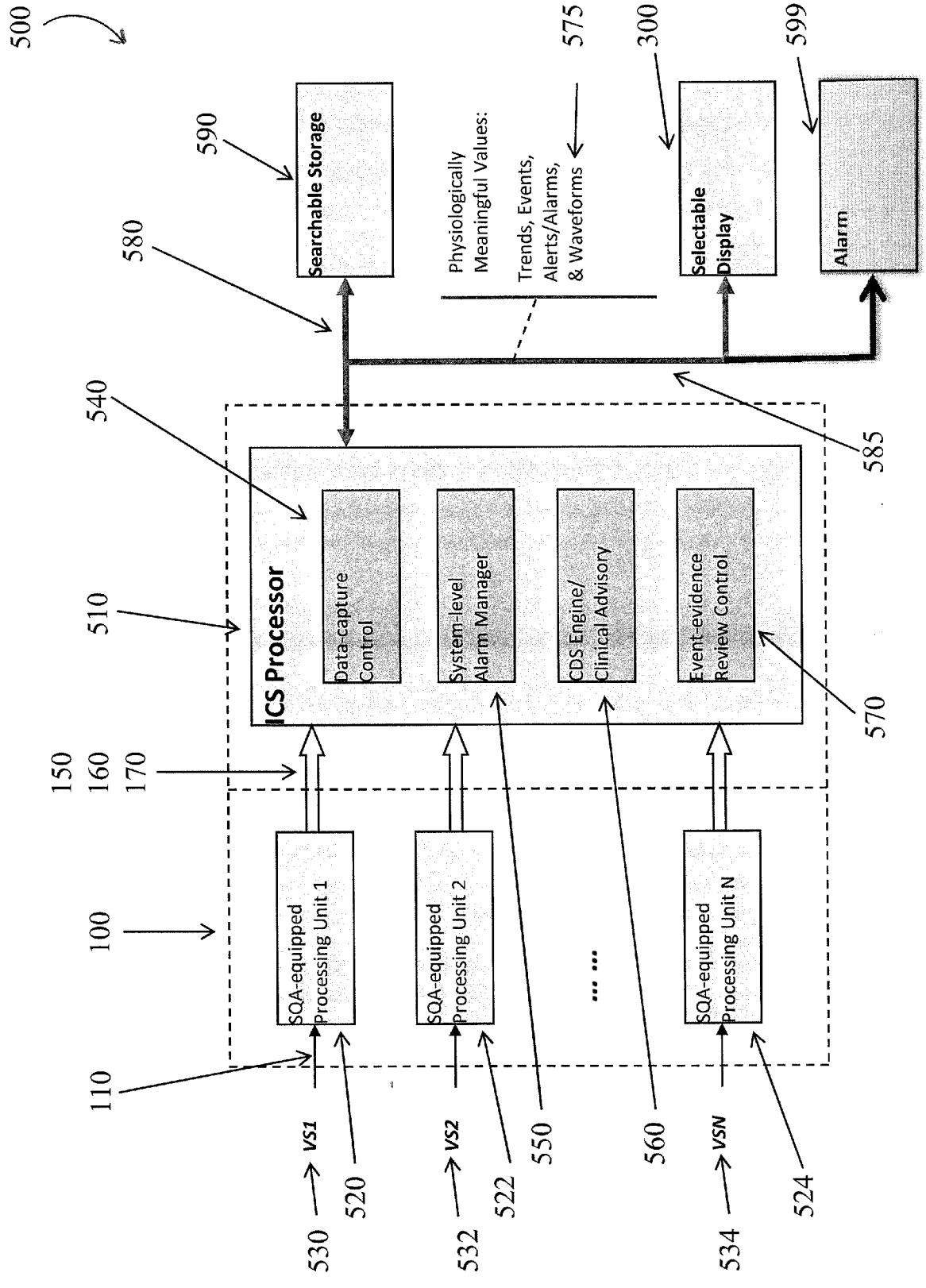
500
590
Searchable Storage
580
Physiologically Meaningful Values:
Trends, Events, Alerts/Alarms, & Waveforms
575
300
Selectable Display
599
Alarm
585
540
ICS Processor
Data-capture Control
System-level Alarm Manager
CDS Engine/ Clinical Advisory
Event-evidence Review Control
570
510
150
160
170
100
SQA-equipped Processing Unit 1
SQA-equipped Processing Unit 2
... ...
SQA-equipped Processing Unit N
110
VS1
VS2
VSN
520
522
524
530
532
534
550
560

Fig. 5

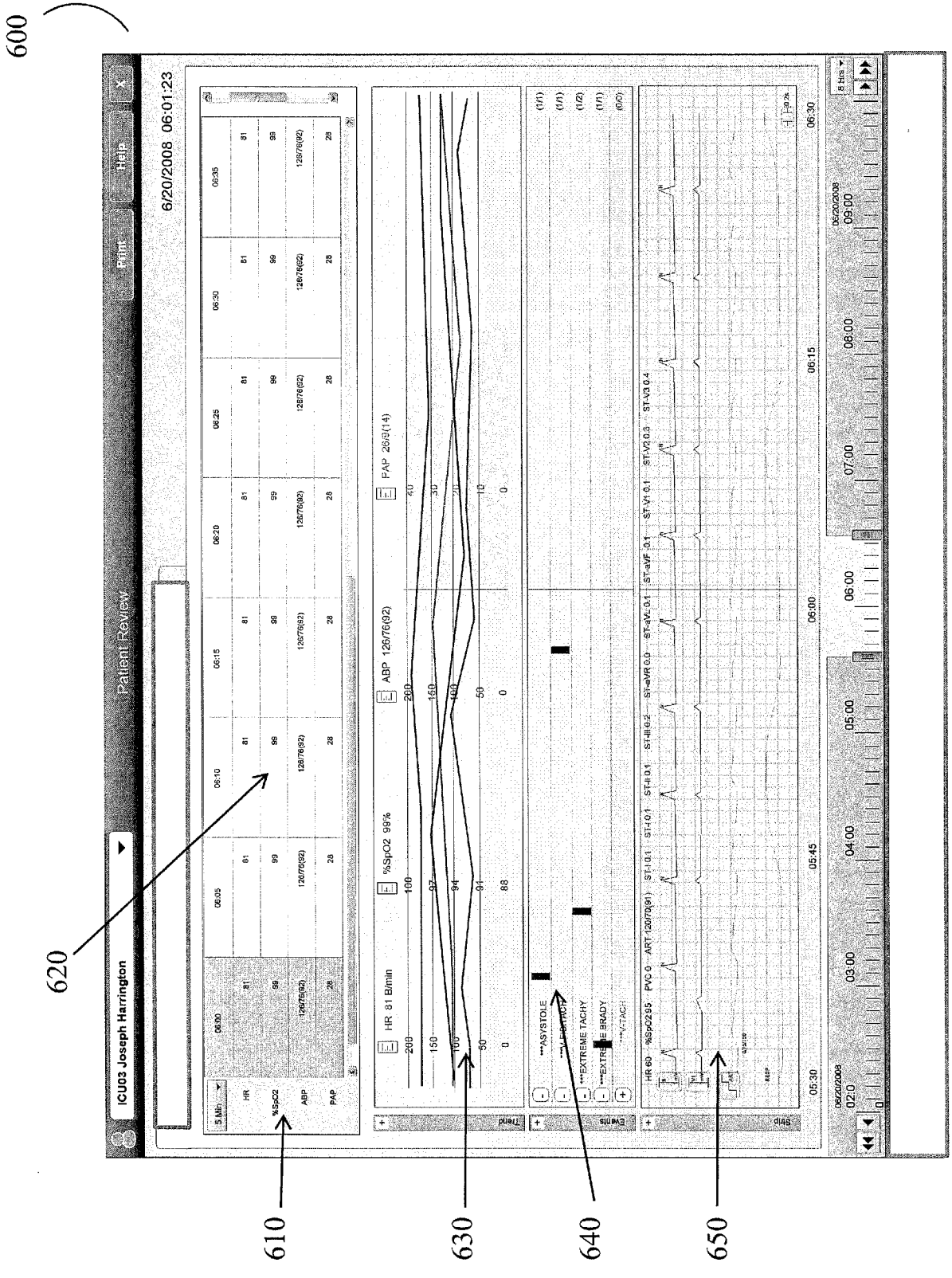
600
620
610
630
640
650
Patient Review
ICU03 Joseph Harrington
Print
Help
6/20/2008 06:01:23
HR 81 B/min
%SpO2 99%
ABP 125/76(92)
PAP 28/9(14)
***ASYSTOLE
***EXTREME TACHY
***EXTREME BRADY
Trend
Events
Strip

Fig. 6

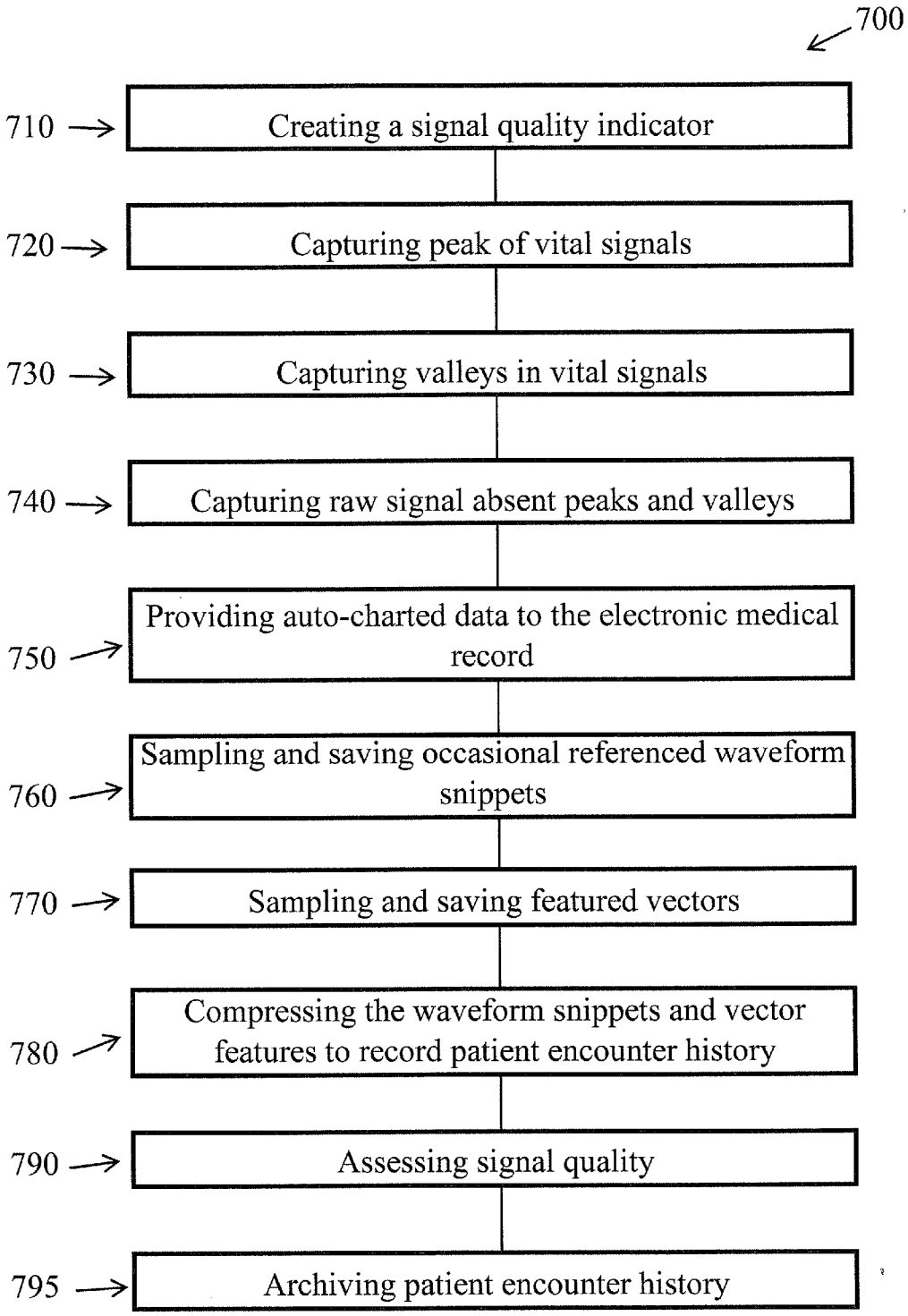
700
710
Creating a signal quality indicator
720
Capturing peak of vital signals
730
Capturing valleys in vital signals
740
Capturing raw signal absent peaks and valleys
750
Providing auto-charted data to the electronic medical record
760
Sampling and saving occasional referenced waveform snippets
770
Sampling and saving featured vectors
780
Compressing the waveform snippets and vector features to record patient encounter history
790
Assessing signal quality
795
Archiving patient encounter history

Fig. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2010/050109

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 G06F19/00
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 G06F

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 190 038 A (POLSON MICHAEL J R [US] ET AL) 2 March 1993 (1993-03-02) column 3, line 41 - line 49 column 11, line 7 - line 58 column 9, line 33 - line 36 column 10, line 11 - line 35 column 8, line 20 - line 30 column 7, line 16 - line 25 figure 7	1-20
X	US 2007/239220 A1 (GREENHUT SAUL E [US] ET AL) 11 October 2007 (2007-10-11) figures 4,5 paragraphs [0037], [0042], [0049], [0052] - [0064]	1-20

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

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"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	Date of mailing of the international search report
9 April 2010	19/04/2010

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Vanderperren, Yves

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2010/050109

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/138540 A1 (BAKER CLARK R [US] ET AL BAKER JR CLARK R [US] ET AL) 15 July 2004 (2004-07-15) paragraphs [0001], [0007] - [0009], [0014], [0020], [0021], [0024] - [0036], [0044] - [0046], [0065]	1-20
X	ABOUKHALIL A ET AL: "Reducing false alarm rates for critical arrhythmias using the arterial blood pressure waveform" JOURNAL OF BIOMEDICAL INFORMATICS, ACADEMIC PRESS, NEW YORK, NY, US LNKD-DOI:10.1016/J.JBI.2008.03.003, vol. 41, no. 3, 1 June 2008 (2008-06-01), pages 442-451, XP022700527 ISSN: 1532-0464 [retrieved on 2008-03-21] page 443 - page 446	1-20
X	EP 1 077 042 A1 (CRITIKON COMPANY L L C [US]) 21 February 2001 (2001-02-21)	1,3-7, 12, 14-17,20
A	figure 1 paragraphs [0007], [0008], [0019], [0023], [0025], [0035], [0046]	8-11,13, 18,19
X	US 5 810 740 A (PAISNER WILLIAM LEE [US]) 22 September 1998 (1998-09-22)	1-5,7, 12-15,17
A	figure 4 column 1, line 8 - line 10 column 2, line 8 - line 67 column 3, line 39 - line 60 column 4, line 66 - column 5, line 5 column 6, line 34 - line 40	6,8-11, 16,18-20

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2010/050109

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5190038 A	02-03-1993	US 5448991 A	12-09-1995
		US 5398680 A	21-03-1995
US 2007239220 A1	11-10-2007	EP 2004285 A2	24-12-2008
		WO 2007117826 A2	18-10-2007
US 2004138540 A1	15-07-2004	CA 2512401 A1	29-07-2004
		EP 1587416 A1	26-10-2005
		JP 2006512973 T	20-04-2006
		WO 2004062492 A1	29-07-2004
		US 2006135860 A1	22-06-2006
EP 1077042 A1	21-02-2001	DE 60037854 T2	22-01-2009
		JP 3742817 B2	08-02-2006
		JP 2001078969 A	27-03-2001
		US 6358213 B1	19-03-2002
US 5810740 A	22-09-1998	WO 9717893 A1	22-05-1997

专利名称(译)	用于自动捕获和存档临床上有意义的生命体征的系统和方法		
公开(公告)号	EP2429381A1	公开(公告)日	2012-03-21
申请号	EP2010702173	申请日	2010-01-12
[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.		
当前申请(专利权)人(译)	皇家飞利浦N.V.		
[标]发明人	NIELSEN LARRY RABER GREGORY H GROSS BRIAN D ZONG WEI SAEED MOHAMMED		
发明人	NIELSEN, LARRY RABER, GREGORY, H. GROSS, BRIAN, D. ZONG, WEI SAEED, MOHAMMED		
IPC分类号	A61B5/00 G06F19/00		
CPC分类号	A61B5/0002 A61B5/0205 A61B5/021 A61B5/02116 A61B5/7203 A61B5/7221 A61B5/7232 G16H15/00 G16H50/20		
优先权	61/152979 2009-02-17 US		
外部链接	Espacenet		

摘要(译)

捕获，记录，处理医学生命体征（110），并且基于诸如斜率，幅度，上升时间，峰值时间和信号峰值的程度的信号波形分量来计算信号质量评估（160）（420））和山谷（430）。信号评估（160）可以用作对基础生命信号的质量（130）进行评级的基础，以通过去除噪声段和生理上不可能的峰（424）和谷（434）来增加信号的质量，以检测参数值（120），标记波形（140），或提示警报（550）以指示信号已达到临界水平并向用户发出生命数据的警告。信号和评估存储在索引的，可搜索的数据存储存储器（590）中，可以从中检索和显示信号（300）。