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(54) **SYSTEM AND DEVICE FOR MULTI-SCALE ANALYSIS AND REPRESENTATION OF ELECTROCARDIOGRAPHIC DATA**

SYSTEM UND GERÄT ZUR ANALYSE UND DARSTELLUNG ELEKTROKARDIOGRAPHISCHER DATEN DURCH MEHRFACHAUFLÖSUNG DER DATEN

SYSTEME ET PROCEDE D'ANALYSE PAR MULTI-RESOLUTION ET DE REPRESENTATION DE DONNEES ELECTROCARDIOGRAPHIQUES

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Description

FIELD OF THE INVENTION

[0001] This invention relates to the filed of electrocardiography and more specifically to a method and apparatus for analyzing electrocardiogram and its serial changes, including small changes that cannot be exposed by conventional analysis, structuring and representing the results in the form understandable both to lay public and medical professionals.

BACKGROUND OF THE INVENTION

[0002] Electrocardiogram is one of the most common medical examinations of cardiac electrical activity, which is performed by a medical professional or paramedics. Registration of ECG is relatively simple, however, its analysis requires a highly qualified physician with substantial experience in electrocardiography.

[0003] In general, there are two types of ECG tests, a one-time recording during a few seconds and a long-term monitoring which can be performed during various physiological tests, regular daily activities or as a round-the-clock monitoring in patients with serious medical disturbances. Each test requires a specialized protocol for registering and analyzing ECG signals.

[0004] One-time ECG recording is usually performed by ECG technicians or paramedics. The recording then is transferred to a physician for analysis, which includes a number of procedures. First, the cardiac complexes are visually identified by their characteristic shape consisting of a sequence of the following waves: P-, Q-, R-, S-, T- and sometimes U-wave. Next, these complexes are classified according to their origin as normal or sinus, supraventricular, ventricular complexes and their subtypes. The distance between two consecutive complexes is measured to determine the heart rate. Next, a number of the most important parameters including the amplitudes of each wave, the duration of PQ, QRS, and QT-intervals, and the amplitude of ST-segment are measured. Finally, the signals are compared with the recordings that were previously obtained from the same patients to determine serial changes in cardiac electrical activity.

[0005] Comparison of serial recordings is an important part of standard ECG examination that allows detection of changes and determining their time course. The comparison is performed visually by an experienced medical professional. The accuracy of this subjective comparison is not high and varies among physicians. The accuracy is not stable even in the same physician when the same measurements are repeated several times.

[0006] There are a number of prior art computerized systems that follow these basic steps of analysis and measure characteristic waves of ECG and prepare preliminary report for a physicians. Since the number of analyzed variables and their combinations is large, these systems use sophisticated processing algorithms that require fast and powerful microprocessors or computers with a large memory available for processing.

[0007] Systems for long-term monitoring consist of two types, recording and real-time systems. Recording systems include 24-hour Holter monitors and event monitors, which record the data after a manual signal (event). Processing of these recordings, which include a large amount of data, consists of computer-assisted scanning with subsequent manual verification by an experienced medical professional. The results of analysis which include average heart rates, number of normal and types of abnormal beats during different periods of time, are submitted to a physician for final verification and conclusion.

[0008] Real-time systems include event-monitors, bedside monitors, stress-test systems and other devices for monitoring 1-2 critically important parameters and generating alarm or presenting the output information on a monitor. These systems perform an incomplete examination tracking the changes in heart rate and sometimes changes in the ST-segment. While this information is important for real-time control of a test or treatment, a number of important ECG changes, including changes in Q-, T-, or P-wave amplitude, QT-duration, are not exposed by this analysis.

[0009] It is known to provide portable ECG monitors that will sound an alarm or other signal to alert the user or an attendant of abnormal or unusual changes in the waveforms of the ECG signal. Such devices are, for example, disclosed in U.S. Patents 4,193,393; 4,679,144; 5,033,475; 5,501,229 and 5,724,983. A system is also known, from U.S. Patent 6,038,469, that includes at least one monitoring module for receiving ECG signals, a circuit for analyzing the signal, a plurality of parameters related to a patient's ischemic condition, and a network for exchanging data with a central unit, either by hard wire or telemetry. The monitor can be used in an ambulatory application in which the ECG signals are recorded and later sent to a central processing unit or units, which may be capable of sending information and data to the portable unit(s).

[0010] Shusterman et al. U.S. Patent 5,967,995 has identified small cumulative changes in the series of cardiac interbeat intervals using the Principal Component Analysis (PCA). This method accurately identified unstable dynamics of cardiac rhythm and predicted cardiac arrhythmias as early as several hours before the event when all known physiological indicators remained normal. The Shusterman et al. invention further extends the applications of PCA to the ECG signal by providing a complete set of descriptors of the ECG dynamics using the time series of other important variables, including QT-interval and T-wave amplitude.

[0011] The publication US-A-6,038,469 discloses a cardiac monitoring and telemedecine system and method using several processing units.

SUMMARY OF THE INVENTION

[0012] This invention provides a portable and easy-to-use system for structured and complete analysis and representation of electrocardiogram and its serial changes quantitatively for medical professionals and qualitatively for a lay patient who does not have any medical background. Structuring of the analysis is achieved by constructing the at least two, and preferably three, information scales that represent the most significant parameters at different level of detail.

[0013] Low, intermediate and high-resolution scales are defined according to the corresponding software and hardware resources. A low-resolution (Scale I) represents a small number of the most important primary elements such as intervals between the heart beats, duration of PQ, QRS, and QT-intervals, amplitudes of P-, Q-, R-, S-, and T-waves. This real-time analysis is implemented in a portable device that requires minimum computational resources. The set of primary elements and their search criteria are adjusted for each ECG utilizing computational resources of intermediate or high-resolution levels. At the intermediate-resolution (Scale II), serial changes in each of the said elements are determined using a mathematical decomposition into series of orthogonal basis functions and their coefficients. This scale is implemented using a specialized processor or a computer organizer. At the high-resolution (Scale III), serial changes in all elements of the ECG and their combinations are extracted using orthogonal mathematical decomposition to provide complete information about the dynamics of the signal. This scale is implemented using a powerful processor, a network of computers or the Internet.

[0014] Scale I may be implemented in a portable, pocket-size device, in which the signal is decomposed into a plurality of primary elements and parameters such as intervals between the heart beats, type of a cardiac complex, amplitudes and duration of P-, QRS, T-, and U-wave, QT-interval, amplitude of ST-segment. Scale I of the system provides the means for real-time electrocardiographic analysis by comparing the primary elements of ECG with reference values (individual thresholds) using the minimum computational resources. The reference values are programmed into the device based on normal values for the primary elements for the patient. Scale I includes means for adjustment of individual thresholds and criteria for rejection of noisy data. A detector of noise and error rejects the noisy data if the primary elements exceed physiologic range. Alternatively, modification of the primary elements and adjustment of their search criteria can be performed automatically at the higher-resolution Scale II or Scale III. In this case, the Scale I analysis is implemented using a programmable microprocessor that can be re-programmed at the higher-resolution scales to account for the individual characteristics of the ECG pattern and monitoring goals. Specific sets of primary elements can be used for patients with different cardiovascular abnormalities.

[0015] Scale I can be used in two modes: static mode and dynamic mode. The static mode is used for one-time ECG examination in which the newly acquired primary elements are compared with the default reference values. The dynamic mode is used for comparison of the newly acquired primary elements and waveforms with the primary elements and waveforms that were previously acquired from the same person. The shapes of QRS, T, and P-waves are compared using cross-correlation function. A small magnitude of the difference between the two measurements permits classifying them as substantially similar and keeping only one measurement in the memory.

[0016] Scale I provides sufficient information for standard, one-time, clinical ECG examination. The most significant primary elements may be represented as a color, symbol, or other easy-to-read encoding of indicators that make the results useful and understandable for a lay person and a medical professional. Each signal-indicator corresponds to a single primary element. In the static mode, the values of the indicators are preferably color-coded for a lay person into normal, moderately or severely abnormal. This representation constitutes a static screen. Alternatively, the indicators may be symbol-coded, N for normal and A for abnormal reading; they may vibrate or produce a sound output for people with vision or hearing impairments. For a medical professional, the indicators provide exact, quantitative values of the primary elements. In the dynamic mode, the indicators are preferably symbol (or color)-coded into C for changed or U for unchanged. This representation constitutes a dynamic screen.

[0017] Intermediate-resolution Scale II allows viewing the ECG with automatically determined primary elements on a display and interactive editing of the set of primary elements and their search criteria. The editing can be performed by a user or a medical professional to modify the set of characteristic points or to adjust their search criteria, and can be performed either manually or automatically by the software. The individually adjusted search criteria can then be used to re-program the Scale I analysis as described earlier.

[0018] Scale II allows accurate comparison of serial ECGs and detection of small serial changes that may be unexposed by visual inspection of the signals. This scale requires higher computational resources than Scale I and can be implemented in a specialized processor, computer organizer or a personal computer. These computational resources also allow manual entering text information about the patient into the database and specific instructions regarding adjustment of time windows, threshold values, and other variables. To perform the Scale II analysis, the primary elements from serial ECGs are stored into a database to construct the time series for each primary element. The series is decomposed

into a few most significant basis functions and coefficients using Principal Component Analysis (PCA) or any other orthogonal set of basis functions. The newly acquired values of the primary elements are compared with the series of the previously obtained values. Furthermore, the changes in the series of PCA coefficients are analyzed to detect small cumulative changes in the dynamics of the series that indicate instability in the cardiac electrical activity.

[0019] High-resolution Scale III is used to analyze individual and combined changes in the primary elements; at this scale, the number of the primary variables is increased to include the entire waveform of the cardiac complexes. This allows the most sensitive and accurate detection of the small changes in the individual electrocardiographic pattern. The same PCA approach is used at this scale to expose small serial changes in the ECG recordings. Scale III requires higher computational resources compared to Scale I and Scale II; it may be implemented in a powerful processing unit such as a personal or specialized computer or a distributed network of computers or the Internet.

[0020] This invention can be used for one-time examinations by patients, medical professionals, paramedics and lay public, and for dynamic assessment of changes in cardiac electrical activity. The information can be transmitted to an external computer system or a network of computers. For a lay person, the system may also include a database explaining significance of the changes in each primary element and providing simple recommendations about the measures that has to be taken if the readings of the indicators become abnormal. These may include complete cessation of physical activity, contacting a medical professional, taking a medication, etc. More detailed recommendations might be provided for patients who have specific abnormalities or medications. These patients might require special monitoring or individual adjustment of their primary elements. For example, specific monitoring the duration of QT-interval is important in patients taking antiarrhythmic drugs that prolong QT-interval.

[0021] The system can be used as

- first-aid ECG analyzer for emergency units, paramedics, and medical personnel;
- ECG analyzer for a routine medical examination;
- a personal one-time or serial ECG analyzer with storage of individual electrocardiographic historic data, adaptive adjustment of individual thresholds and assessment of changes in individual ECG pattern;
- a one-time or serial ECG analyzer for a group of people, a family or a patient group, with storage of individual electrocardiographic historic data for each person, adjustment of individual thresholds and assessment of changes in individual ECG patterns;
- event-monitoring device including patient-detected events, changes in heart rate or ST-segment;
- arrhythmia, bed-side, stress-test monitoring;
- pacemaker and other implantable device checking;
- evaluation of the treatment efficacy, side effects and progression of the disease.

[0022] Accordingly, an object of this invention is to provide a system for analyzing ECG signals at least at two levels of detail or resolution. Both levels of resolution are presented in simple representation that can be understood by lay persons, as well as medical professionals.

[0023] A further object of this invention is to provide an ECG analyzing system that includes a monitoring device for receiving and analyzing ECG signals and which includes means for communicating with an external computer to which the ECG signals can be forwarded for more complex analysis. The monitoring device can be reprogrammed by the external computer to select the primary elements of the ECG signals that are unstable or abnormal. The low level analysis performed by the monitoring device is thus focused on the critical primary elements for that patient.

[0024] The above and other objects and advantages of this invention will be more fully understood and appreciated by reference to the following description and the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] A full understanding of the invention can be gained from the following description of the preferred embodiments when read in conjunction with the accompanying drawings in which:

FIG. 1 is a block diagram of the medical device of the preferred embodiment of this invention.

FIG. 2 is a block diagram of the analysis unit from FIG. 1.

FIG. 3 shows the set of indicators that represent the results of ECG analysis at Scale I both qualitatively and quantitatively in a static mode ("N" denotes normal value and "A" denotes an abnormal value of a characteristic parameter).

FIG. 4 shows the set of output indicators that represent the results of ECG analysis at Scale I both qualitatively and quantitatively in a dynamic mode ("U" represents unchanged value and "C" represents a changed value of a characteristic parameter compared to a previous recording).

FIG. 5 is a flowchart of operation of the preferred embodiment.

FIG. 6 is a graph of a representative electrocardiogram from a normal subject and its segmentation into a plurality of characteristic points and segments.

FIG. 7 is a graph of a representative electrocardiogram from a patient with a cardiac disease, large Q-wave, and prolonged QT-interval (0.5 sec) compared to the normal ECG shown in FIG. 6.

FIG. 8 shows the readings from the output indicators at Scale I in the static mode for the abnormal ECG in FIG. 6 (N denotes normal value, A denotes abnormal value of a characteristic parameter compared to default values).

FIG. 9 is a graph of ECG obtained from the same patient as in FIG. 8 several hours later. The amplitude of T-wave decreased by 0.3 mV compared to the previous recording shown in FIG. 7.

FIG. 10 shows the readings from the indicators at Scale I in the dynamic mode for the abnormal ECG in FIG. 9.

FIG. 11 shows the time series of QT-intervals (panel A) and its first three PCA-coefficients (panels B-D) in patient A during one month.

FIG. 12 shows the time series of T-wave amplitudes (panel A) and its first three PCA-coefficients (panels B-D) in patient A during one month.

FIG. 13 shows serial ECG tracings of patient A during one month.

FIG. 14 is a plot of the first PCA-coefficient obtained from the series of QT-intervals versus the first PCA-coefficient obtained from the series of T-wave amplitudes in patient A.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0026] FIG.1 is a block-diagram of a preferred embodiment of a medical device 10 of this invention. The device consists of an acquisition unit 20 that may have several electrodes 25 for attachment to a patient, not shown, to receive electrocardiographic signal, an analysis unit 40, an optional output unit 60, an action unit 80 and a communication unit 100. Standard ECG recorders having acquisition units and storage units are available from several companies such as Hewlett-Packard (Model 1700A) and GE Marquette Medical systems (Mac 500). Portable ECG monitors that record and store segments of ECG are available from Integrated Medical Devices (Model 1200). The acquisition part may receive ECG data from a recorded data source for analysis, but preferably receives the data real-time, on-line through the electrodes 25 that are connected to a patient. As used herein, patient means an animal, and most likely a human. The medical device further includes an analysis unit or module 40 which, in turn, consists of processing, compression, storage, and comparison units (FIG. 2). The processing unit 41 can be a typical computer or personal computer of the type available from many vendors such as IBM and Hewlett-Packard. The processing unit 41 is programmed to detect a plurality of characteristic points such as the onset, peak and offset of P-, Q-, R-, S-, T-, U-waves, and computes the characteristic parameters or primary elements which include amplitudes of the said waves and ST-segment, duration of PO-, ORS-, and QT-intervals. The processing unit 41 has a programmable microprocessor that can be programmed to modify or change the set of primary elements or to adjust their search criteria. This allows individual adjustment of the characteristic points which, in turn, increases the accuracy of detection of the primary elements. For instance, in signals with biphasic T-wave, two T-peaks should be detected, whereas monophasic T-wave requires detection of a single T-peak. Furthermore, the criteria for determining the offset of biphasic T-wave are different from the criteria for the offset of monophasic T-wave. Individual adjustment of the primary elements and their search criteria increases the accuracy of the detection of characteristic points in different ECG patterns. Still another possibility is analysis of combined changes in some primary elements or disabling analysis of the other elements. For example, in patients with possible electrolyte abnormalities, the amplitudes of the T-wave and U-wave may be combined into a single index which will be convenient for monitoring. Furthermore, the set of monitored primary elements can be modified according to the specifics of cardiovascular abnormality. For example, in patients with coronary artery disease, the amplitude and the slope of the ST-segment should be monitored continuously.

[0027] Compression unit 42 compresses the ECG waveform into a few weighted basis vectors and their coefficients using principal component analysis, wavelet decomposition, or other orthogonal mathematical transformation. Storage unit 43 stores the compressed waveforms and the computed primary elements into memory. Comparative unit 44 compares the newly acquired waveforms and newly computed primary elements with the waveforms and primary elements previously stored in the storage unit 43. The analysis unit 40 has means for adjusting the thresholds for each indicator, whereas the default values correspond to normal ECG. An output unit 60 includes a screen or a set of indicators for displaying the ECG waveforms and the computed primary elements in comparison with the previously stored primary elements or in comparison with the default reference values. The results of comparison can be represented both qualitatively and quantitatively in the dynamic and static modes. In the static mode, the quantitative representation includes exact values of the primary elements and the type of the cardiac complexes, whereas the qualitative representation includes indication of each parameter as being normal (N) or abnormal (A) as shown in FIG 3. Abnormal readings may be further classified into moderately abnormal and severely abnormal. To make the indicators understandable to a lay person, the degree of abnormality may be color-coded: green color corresponds to a normal value, yellow corresponds to a moderate abnormality, and red corresponds to a severe abnormality. In the dynamic mode, the quantitative repre-

sentation shows the differences between the newly acquired and stored primary elements and waveforms, whereas the qualitative representation includes indication of each parameter as being changed (C) or unchanged (U) as shown in FIG. 4. The output unit 60 may alternatively or additionally feed an output data to an action unit 80 for sounding an alarm, generating a vibration, or taking appropriate measures, such as applying the drugs or adjusting the therapy mode. Communication unit 100 transmits the information between the device 10 and external higher-level processing device 150. The communication unit 100 may be a modem or a wireless transmitter/receiver. Electrocardiographic signals and recorded values of primary elements and indexes are transmitted from the device 10 to higher level devices for more detailed processing and storage. The higher-level device 110 preferably transmits back to device 10 a set of primary elements and their search criteria to be used in device 10.

[0028] FIG.5 is a flow-chart of operation of this medical device.

[0029] FIG. 6 shows a representative ECG obtained from a normal subject and position of the characteristic points in the signal.

[0030] To achieve the optimal sensitivity in the detection of hidden or small ECG changes, a pattern recognition approach is used that extracts the basis functions from the statistics of the signal itself and gives the least error representation of the signal. Specifically, a principal component analysis (PCA) is applied which requires a minimum number of basis functions to obtain a fixed reconstruction error compared to other orthogonal expansions.

[0031] PCA is an orthogonal transformation that employs a weighted combination of several basis functions to represent a signal. The basis functions are fixed, whereas PCA-coefficients vary as a function of time. The choice of PCA for detection and characterization of the changes in ECG-signal was related to the following properties of the transform:

- minimization of the mean square error within a finite number of basis functions guarantees that no other expansion will give a lower approximation error (with respect to the mean square error).
- clustering transformational properties with minimization of the entropy in terms of the average squared coefficients used in the expansion.

[0032] In contrast to the methods that use fixed-form basis functions (for example, Fourier representation), basis functions in PCA are derived from the statistics of the signal. Therefore, PCA with the same number of basis functions provides a smaller residual error than other expansions.

[0033] Assume that the pattern contains M vectors x_i i = 1,2,..., M, and the length of each vector is equal to N points. To obtain the PCA coefficients, the matrix C_x must be obtained using the average of the covariance matrices of x vectors. The matrix C_x is defined as

$$C_x = E\{(x - m_x)(x - m_x)^T\} \qquad (1)$$

where

$$m_x = E\{x\} \qquad (2)$$

is the mean vector, and E corresponds to the expected value. Assume that the pattern of the time series has M unit-length vectors x_i, i = 1,2,..., M, and the length of each vector is equal to N points, to generate a matrix C_x from the outer products of vectors x. A matrix C_x of M vectors x_i can be calculated as

$$C_x \cong \frac{1}{M}\sum_{i=1}^{M}\{(x_i - \hat{m}_x)(x_i - \hat{m}_x)^T\}, \qquad (3)$$

where $i=1,2,...M,$ and

$$\hat{m}_x \cong \frac{1}{M}\sum_{i=1}^{M} x_i \qquad (4)$$

[0034] From the matrix C_x one can obtain eigenvectors ψ_i i = 1,2,.., N and corresponding eigenvalues λ_i i = 1,2,...., N. Let A be the transformation matrix whose rows are the eigenvectors of C_x. First eigenvector corresponds to the first eigenvalue, second one corresponds to the second eigenvalue and so on. Eigenvalues are arranged in decreasing order so that $\lambda_1 \geq \lambda_2 \geq ... \geq \lambda_N$. Then, PCA consists of a multiplication of the transformation matrix A by vector $(x - m_x)$:

$$y = A(x - m_x) \qquad (5)$$

where y is a PCA coefficient vector. If matrix A is formed by K eigenvectors that correspond to the largest eigenvalues, y is a K $\times$ 1 vector. Then, the first K coefficients contain almost entire information about the signal allowing substantial reduction in the number of analyzed coefficients and thus compression of the data. In this application, PCA is applied to the time series of each primary element, that is the intervals between the cardiac beats, duration of PQ, QRS, and QT-intervals, amplitudes of P-, Q-, R-, S-, and T-waves. For instance, to determine the characteristic pattern of the series of QT-intervals from the serial ECGs, assume that the pattern consists of M unit-length vectors x_i. Therefore, the series is divided into M constant-length time windows to obtain vectors x_i. Alternatively, the unit-length vectors x_i may be comprised of a combination of all or some primary elements to determine a typical combinatorial pattern of the primary elements. Still another possibility is an extension of the concept of the unit-length vectors x_i into two dimensions to represent both the combined pattern of all primary elements (in the first dimension) and the serial changes of each primary element (in the second dimension). Then PCA analysis is performed as described above.

Applications of the Principal Component Analysis at Scale H and Scale III of the System

[0035] In previous works, PCA was applied for detection and classification of cardiac waveforms (QRS-complexes and ST-segments) in ECG. The optimal basis functions for QRS or ST waveforms were obtained from large training sets. PCA coefficients were used to compare individual waveforms with the set of templates and to assign the waveform to one of the classes.

[0036] Instead of applying PCA to the signal as in the previous art studies, this invention preferably applies PCA to the time series of primary elements that are extracted from the ECG-signal. This modification provides the following advantages. First, this provides an objective and accurate estimation of the serial changes in the ECG-signals and reveals small or hidden abnormalities that cannot be exposed by the previously used techniques. Second, this allows dramatic compression of the data. Third, this analysis reveals independent changes in each primary element when simultaneous changes occur in several elements. The prior art analysis of the original ECG signal might not show any changes because of the cancellation effects between the elements undergoing changes in opposite directions.

[0037] Because the time series of primary elements is nonstationary and highly variable among subjects and in the same subject over different periods of time, typical waveforms or templates of this series cannot be determined. Therefore, temporal, adaptive changes in PCA coefficients are used to detect and characterize the changes in this series. Pronounced and complex changes in the series of primary elements are identified by the simultaneous changes in several PCA coefficients. Since the basis functions in this expansion are orthogonal, simultaneous changes in several coefficients represent complex disturbances in linearly independent components of the signal. These combined changes in PCA coefficients reveal serious instabilities in the cardiac function as shown in the following examples.

[0038] The signal is separated into consecutive windows, and an array of vectors is obtained from the series. A covariance matrix is formed by the formula (3), where M is the number of vectors, x_i is i^{th} vector, and m_x is calculated as in formula (4). Basis functions or eigenvectors are obtained from this matrix. Since only one covariance $N \times N$ matrix (N is the window length) is generated from the signal, all eigenvectors are fixed.

Example

[0039] The following example illustrates the sequence of ECG analysis at the system's Scales I, II and III. Serial ECG recordings from a patient A who had a structural heart disease and dynamic changes in the electrocardiogram were processed at each Scale with a different degree of detail. Scale I revealed the changes in a small number of important, primary elements using minimum computational resources. Scale II exposed changes in the primary elements that occurred in serial recordings over time. Scale III provided complete description of the serial ECG changes using a complete set of primary elements and their combinations.

[0040] **System initialization.** When the system is used for the first time, initialization is required for verification and individual adjustment of the analysis criteria including identification of the primary elements and their search criteria. System initialization is performed using the hardware and software resources of the intermediate resolution Scale II and high resolution Scale III. In the initialization mode, the Scale I device transmits ECG to the higher Scale of the system

via a direct or a wireless (telemetry or infrared) link. The ECG and the position of primary elements and their characteristic points (onset, peak, and offset) are visualized on a display, for example LCD display, as shown in FIG. 6. The position of characteristic points can be verified and manually edited by a user, a lay person or a medical professional. A simple manual or a software tutoring program of the typical ECG patterns, the primary elements and their characteristic points is provided for a lay person. FIG. 7 shows an ECG with a long QT-interval (0.5 sec) and a low-amplitude T-wave compared to the normal ECG shown in FIG. 6. The offset of this low-amplitude T-wave is difficult to detect automatically and a manual verification and correction are desired to ensure the accuracy. A user may also modify the set of monitored primary elements to account for a specific cardiovascular abnormality. Some of the elements may be combined into a single monitoring index, for example, a combined integral of T and U peaks can be useful for patients with possible electrolyte abnormalities.

[0041] After finishing manual verification and editing, the system automatically adjusts the search criteria for each characteristic point which include the time window, the amplitude, integral and derivative thresholds. The individually adjusted program is generated for a particular person and is automatically sent to re-program the processing sub-unit of Scale I. After the initialization, the Scale I device can work in autonomous regime without permanent connection to the higher-level Scales.

[0042] Re-initialization and serial adjustment can be performed to modify the set of primary elements and indexes and their search criteria. In addition to the procedure that was described in the system initialization, the results of the Scale II analysis can be used for serial adjustment. In particular, the primary elements and indexes whose time series and PCA coefficients demonstrate unstable behavior can be identified and included into the Scale I analysis.

[0043] **Scale I.** FIG. 7 is a graph of a representative electrocardiogram which has large Q-wave, and prolonged QT-interval. These abnormalities have been detected by the method of the present invention at the Scale I and represented qualitatively as abnormal findings and quantitatively as the exact magnitude of changes compared to the default values as shown in FIG. 8 which are readings of output indicators at Scale I for abnormal (A) and normal (N) ECG in the static mode. FIG. 9 is a graph of ECG obtained from the same patient several hours later. The amplitude of T-wave decreased by 0.3 mV compared to the previous recording shown in FIG. 8. The amplitude of T-wave decreased by 0.3 mV compared to the previous recording shown in FIG. 7. FIG. 9 shows the readings from the output indicators that represent the changes (C) in this ECG compared to the previous one.

[0044] **Scale II.** Serial ECGs have been obtained from patient A. and processed by means of Scale II to expose the time course of the serial changes that occurred in the this patient over a period of 1 month. Figure 11, panel a, represents the series of QT-intervals that were extracted from these recordings; panels b-d demonstrate the changes in the first three PCA-coefficients that were obtained from this signal. At the end of the last recording, the patient developed a life-threatening disorder of cardiac function. However, this method reveals instability in the cardiac function as early as 20 days before the event when all known physiological indicators remain normal. Figure 12 demonstrates changes in the T-wave amplitude extracted from the same recordings (panel a) and the corresponding first three PCA- coefficients. The time series are complex and the changes cannot be easily described or analyzed by simple tools, therefore, the changes in the signal are analyzed in a compressed form using the series of the first three PCA-coefficients which contain the most significant information about the signal. The ECG was relatively stable during the first 10 days but then became unstable as reflected by variations in the PCA-coefficients. The patient suffered a life-threatening cardiac disorder at the end of the month. However, variations in the PCA-coefficients were observed long before the event, when all physiological indicators remained normal. Calculating the changes in the variance of the PCA coefficients provides an accurate estimation of the changes and stability of the series. Unlike linear estimators such as the mean and variance of the signal or nonlinear estimators such as fractal scaling exponent or correlation dimension, disturbances in the PCA coefficients are indicative of any changes in the pattern of the signal. Therefore, analysis of PCA coefficients reveals both linear and nonlinear changes in the signal.

[0045] **Scale III.** The same ECGs that were analyzed at the Scales I and II, were further processed by means of Scale III to expose the entire dynamics of the ECG signal. Figure 13 demonstrates the ECG waveforms that were obtained from serial ECG recordings in patient A. Since all the data points are included into the analysis, the changes in the shape and polarity of T-wave can be easily detected in the serial ECGs using visual inspection, PCA or other signal processing tools. The polarity of the T-waves are negative in days 2 and 10 recordings, and are positive in days 6, 16 and 25 recordings.

[0046] Figure 14 shows the changes in the PCA coefficients of these series in Scale III, dynamics of ECG in patient A in a space of the first, most significant PCA-coefficients. Y-axis represents the first PCA-coefficient that was obtained from T-wave amplitude. X-axis represents the first PCA-coefficient that was obtained from QT-interval. Each point corresponds to one-hour value. Values during 1-5 days are marked as pluses, values during 6-10 days are marked by stars, values during 11-16 days are marked by circles. Higher dispersion and change in the location of the points during 6-16 days compared to the first five days indicates instability of serial ECGs. A small cluster of data points in the lower right corner of the figure corresponds to the unchanged signals during the first 5 days of the recording. Then, the dispersion of the points increases and their location changes which reflects increased instability of the signals. Thus, the combined changes in the coefficients that were obtained from different primary elements revealed instability in the

cardiac activity that preceded aggravation of the cardiac disease.

[0047] It is therefore seen that this invention provides an ECG analysis system and method for detecting a plurality of primary elements in an ECG signal, and comparing the detected signals with reference values both quantitatively and qualitatively. The outputs from the system in both low level resolution and higher levels of resolution can be understood by both lay persons and medical professionals. The system includes means for exchanging information and direction from an external computer for analysis and modification of the low resolution analysis of the signal.

[0048] Whereas particular aspects of the method of the present invention and particular embodiments of the invention have been described for purposes of illustration, it will be appreciated by those skilled in the art that numerous variations of the details may be made without departing from the invention as described in the appended claims.

Claims

1. A method for dynamic analysis of electrocardiographic (ECG) data in at least two levels of detail, said method comprising:

   collecting ECG signals from a subject;
   analyzing a limited number of primary elements in said ECG data, referred to as low resolution analysis, and comparing said primary elements with at least one reference value to detect one-time changes in such primary elements and thereby identify abnormal or unstable primary elements;
   analyzing serial changes in said ECG data, referred to as high resolution analysis, using at least one method selected from mathematical decomposition and pattern recognition to provide characterization of serial changes in said abnormal or unstable primary elements;
   exchanging information between said analysis in low resolution and said high resolution; and
   adjusting said analyzing based on said characterization of serial changes in the primary elements.

2. A method as set forth in claim 1 in which said analyzing in high resolution further includes:

   combining a plurality of said serial changes in the abnormal or unstable primary elements and analyzing the combined changes using mathematical decomposition; and
   selecting a combination of parameters for tracking the changes in said abnormal or unstable elements and sending information respecting the selected combination to said low-resolution analysis for adjustment of monitoring parameters.

3. A method as set forth in claim 1 in which said analyzing in high resolution comprises:

   forming a time series from said serial changes;
   characterizing said time series using Principal Component Analysis (PCA) and generating PCA-coefficients indicative of both linear and nonlinear changes in the individual pattern; and
   determining the magnitude of said linear and nonlinear changes by using time varying mean and variance of said PCA-coefficients and determining the complexity of said linear and nonlinear changes by calculating the number of PCA- coefficients that exhibit substantially simultaneous changes.

4. A method as set forth in claim 1 in which said analyzing in high resolution comprises:

   forming time series from said serial changes; characterizing said time series using Principal Component Analysis (PCA) and generating PCA-coefficients indicative of both linear and nonlinear changes in the individual pattern; presenting said PCA-coefficients as a vector in n-dimensional space wherein n is the number of variables analyzed; and
   determining the magnitude and direction of the combined changes in the characteristic variables by the changes in the magnitude and direction of said n-dimensional vector.

5. A method as set forth in claim 1 in which said low level resolution includes comparing said primary elements with normal values for such primary elements, and representing deviation of primary elements from the normal values in a form understandable to a lay person.

6. A method as set forth in claim 5 that further comprises representing deviations of said primary elements from said normal values in a quantitative form for use by a medical professional.

7. A method as set forth in claim 1 which includes sounding an alarm when said low resolution detects an abnormal or unstable primary element.

8. An electrocardiographic ECG system for detection and analysis of serial changes in ECG data in at least two levels of detail, said system comprising:

an acquisition unit for collecting ECG signals from a subject over a period of at least several seconds;
a first analysis and processing unit for detecting at least one of a plurality of primary elements from said ECG data and processing said at least one of a plurality of primary elements, referred to as low resolution analysis, to generate data respecting said at least one of a plurality of primary elements;
at least one storage unit for storing at least one reference value of said plurality of primary elements;
a comparative unit for comparing said at least one reference value with data newly received from said first analysis and processing unit and producing at least one_indicator of differences between said at least one reference value and said newly received data;
a second analysis unit for assessing changes in serial ECG data, referred to as higher resolution analysis, and characterizing time series of at least one primary element or index in said set of primary elements and indexes in higher resolution using at least one method selected from mathematical decomposition and pattern recognition; and
a communications unit for exchanging information between said processing in low resolution and said higher resolution so that adjustments can be made in said processing.

9. An ECG system as set forth in claim 8 in which said first analysis unit includes means for receiving commands from said second analysis unit to adjust the primary elements to be detected from ECG signals.

10. An ECG system as set forth in claim 8 which includes at least one output unit for qualitative representation including at least one static screen for one-time ECG presentation and a dynamic screen for presenting changes in serial ECG recordings,

11. An ECG system as set forth in claim 8 in which said set of primary elements includes at least one indicator selected from a complete set of characteristic fragments of the ECG signals and their parameters, said set of characteristic fragments including P, Q, R, S, T and U waves, ST- segment, PR, QRS and QT-intervals, said parameters including the amplitude and duration of said waves and segments, and the time intervals between the heart beats.

12. An ECG system as set forth in claim 8 in which said set of primary elements includes the amplitudes of the T-wave and U-wave combined into a single index for patients with known electrolyte abnormalities.

13. An ECG system as set forth in claim 9 in which said output unit includes a screen for displaying at least one of said qualitative indicators of a minimal set of most significant indexes to indicate a substantially abnormal condition and a screen for quantitative representation that represents a set of characteristic fragments and their parameters.

14. An ECG system as set forth in claim 8 in which said first analysis and processing unit includes means for decomposing the ECG signals into a plurality of elements, and said decomposing means performs an orthogonal decomposition to extract the most significant information about the ECG signals.

15. An ECG system as set forth in claim 8 in which said first analysis and processing unit, storage unit and comparative unit are combined in one pocket size unit connected to said communication unit.

16. An ECG system as set forth in claim 15 in which said communication unit is wireless.

17. An ECG system as set forth in claim 15 in which said storage unit includes storage for a physiologic range of the primary elements and detector of error and noise to reject the data upon detection of the primary elements or the indexes beyond the physiologic range.

18. An ECG system as set forth in claim 8 in which said output unit includes a display for viewing at least one of the ECG signals.

19. A system as set forth in claim 8 in which said means for collecting and storing is a pocket-size unit having wireless communication with the rest of the portable electrocardiograph.

20. A system as set forth in claim 8 in which said set of reference values includes characteristic values for said set of primary elements and indexes previously stored or default characteristic values.

21. An ECG system as set forth in claim 8 in which said means for representing includes an LCD display for viewing the ECG signal, said LCD display representing a range of normal or previously stored values for plurality of characteristic points and segments.

22. Apparatus for detection and analysis of at least one of ECG signals and physiological signals in at least two levels of detail (or resolution) and displaying changes detected in said at least one of ECG signals and physiological signals, said system comprising:

an acquisition unit for receiving signals generated by monitoring a subject for at least several seconds;
an analysis module for detecting at least one of a plurality of primary elements from said signals to detect one-time changes in said at least one of a plurality of primary elements, referred to as low resolution analysis, and thereby identify any abnormal or unstable primary elements;
a storage unit for storing at least one reference value respecting said plurality of primary elements;
a comparative unit for comparing said at least one reference value from said storage unit with at least one of a plurality of primary elements newly received from said analysis module and producing at least one of qualitative indicators and quantitative indicators representing the differences in the data; and
a communications unit for exchanging data with a remote analysis and comparison unit for high level analysis of said signals, said remote analysis and comparison unit using at least one method selected from mathematical decomposition and pattern recognition to provide detailed characterization of serial changes in said abnormal or unstable primary elements and wherein said analysis unit includes means for receiving commands from said remote analysis and comparison unit to reprogram said analysis units,

23. Apparatus as set forth in claim 22 in which said analysis module and said comparative unit analyze and compare data in at least three levels of detail,

24. Apparatus as set forth in claim 23 in which said analysis module includes means for using said commands from said remote analysis unit to modify the primary elements to be detected from said signals.

25. Apparatus as set forth in claim 22 which forms a time series from said serial changes, characterizes said time series using mathematical decomposition adapted for Principal Component Analysis (PCA) and generates PCA-coefficients indicative of both linear and nonlinear changes in the individual pattern, determines the magnitude of said linear and nonlinear changes by using time varying mean and variance of said PCA-coefficients and determines the complexity of said linear and nonlinear changes by calculating the number of PCA-coefficients that exhibit substantially simultaneous changes.

26. A method as set forth in claim 1 in which said analyzing in high resolution comprises:

forming a time series from said serial changes;
characterizing said time series using mathematical decomposition adapted for Principal Component Analysis (PCA) and generating eigenvectors and eigenvalues indicative of both linear and nonlinear changes in the individual pattern; and
determining the magnitude and complexity of said linear and nonlinear changes by comparing the corresponding eigenvectors and eigenvalues.

27. An ECG system as set forth in claim 8 in which said means for characterizing time series of at least one primary element or index also generates eigenvectors and eigenvalues.

28. An ECG system as set forth in claim 8 in which said at least one reference value is selected from among normal values, individual's data, primary elements generated by said first analysis and processing unit, values generated by second analysis unit, manually edited reference values, programmed reference values, default reference values, and series of previously obtained values.

29. An ECG system as set forth in claim 8, which is implemented for at least one of the following settings selected from one-time examinations by patients, medical professionals, paramedics and lay public, for dynamic assessment of changes in cardiac electrical activity, first-aid ECG analysis for emergency units, paramedics, and medical personnel,

for a routine medical examination, a personal one-time or serial ECG analysis with storage of individual electrocardiographic historic data, adaptive adjustment of individual thresholds and assessment of changes in individual ECG pattern, a one-time or serial ECG analysis for a group of people, a family or a patient group, with storage of individual electrocardiographic historic data for each person, adjustment of individual thresholds and assessment of changes in individual ECG patterns, event-monitoring, tracking changes in heart rate or ST-segment, arrhythmia, bed-side, stress-test monitoring, pacemaker and other implantable device checking, evaluation of the treatment efficacy, side effects and progression of the disease,

30. An ECG system as set forth in claim 8, which includes at least one of the components selected from a database explaining significance of the changes in each primary element, providing simple recommendations about the measures that have to be taken if the readings of the indicators become abnormal, including complete cessation of physical activity, contacting a medical professional, taking a medication, more detailed recommendations for patients who have specific abnormalities or medications, special monitoring, individual adjustment of the primary elements for patients with specific abnormalities or medications, monitoring the duration of QT-interval.

31. A method as set forth in claim 1, in which the analysis is applied for at least one of one-time examinations by patients, medical professionals, paramedics and lay public, for dynamic assessment of changes in cardiac electrical activity, first-aid ECG analysis for emergency units, paramedics, and medical personnel, for a routine medical examination, a personal one-time or serial ECG analysis with storage of individual electrocardiographic historic data, adaptive adjustment of individual thresholds and assessment of changes in individual ECG pattern, a one-time or serial ECG analysis for a group of people, a family or a patient group, with storage of individual electrocardiographic historic data for each person, adjustment of individual thresholds and assessment of changes in individual ECG patterns, event-monitoring, tracking changes in heart rate or ST-segment, arrhythmia, bed-side, stress-test monitoring, pacemaker and other implantable device checking, evaluation of the treatment efficacy, side effects and progression of the disease.

32. An ECG system as set forth in claim 8 in which at least one of said acquisition unit, a first analysis and processing unit, a storage unit, a comparative unit, a communications unit, and a second analysis unit is implemented using at least one of a specialized processor, a personal computer, and a computer organizer.

33. Apparatus as set forth in claim 22 in which at least one of said acquisition unit, an analysis unit, a storage unit, a comparative unit, an output unit, a communications unit, and a remote processing unit is implemented using at least one of a specialized processor, a personal computer, and a computer organizer.

34. An ECG system as set forth in claim 32 in which at least one of said output units represents deviations of primary elements from reference values using at least one color-coded scale or symbol-coded scale.

35. Apparatus as set forth in claim 33 in which at least one of said output units represents deviations of primary elements from reference values using at least one color-coded scale or symbol-coded scale,

36. An ECG system as set forth in claim 8 in which said processing and detailed analysis of serial changes is implemented using at least one of a powerful processor, a network of computers, and the Internet.

37. Apparatus as set forth in claim 22 in which said processing and detailed analysis of serial changes is implemented using at least one of a powerful processor, a network of computers, and the Internet.

Patentansprüche

1. Verfahren zur dynamischen Analyse von elektrokardiographischen bzw. EKG-Daten in mindestens zwei Detaillierungsgraden, mit den folgenden Schritten:

Sammeln von EKG-Signalen von einem Subjekt;
Analysieren einer begrenzten Anzahl von primären Elementen in den EKG-Daten (als Analyse mit niedriger Auflösung bezeichnet) und Vergleichen der primären Elemente mit mindestens einem Referenzwert, um einmalige Änderungen in solchen primären Elementen zu detektieren und **dadurch** abnorme oder instabile primäre Elemente zu identifizieren;
Analysieren von seriellen Änderungen in den EKG-Daten (als Analyse mit hoher Auflösung bezeichnet) unter

Verwendung mindestens eines Verfahrens, das aus mathematischer Zerlegung und Mustererkennung ausgewählt wird, um eine Charakterisierung serieller Änderungen in den abnormen oder instabilen primären Elementen bereitzustellen;
Austauschen von Informationen zwischen der Analyse in niedriger Auflösung und der hohen Auflösung und Justieren des Analysierens auf der Basis der Charakterisierung serieller Änderungen in den primären Elementen.

2. Verfahren nach Anspruch 1, bei dem das Analysieren in hoher Auflösung ferner folgendes umfaßt:

Kombinieren mehrerer der seriellen Änderungen in den abnormen oder instabilen primären Elementen und Analysieren der kombinierten Änderungen unter Verwendung mathematischer Zerlegung und
Auswählen einer Kombination von Parametern zum Verfolgen der Änderungen in den abnormen oder instabilen Elementen und Senden von die gewählte Kombination respektierenden Informationen zu der Analyse mit niedriger Auflösung zur Justierung von Überwachungsparametern.

3. Verfahren nach Anspruch 1, bei dem das Analysieren in hoher Auflösung folgendes umfaßt:

Bilden einer Zeitreihe aus den seriellen Änderungen;
Charakterisieren der Zeitreihe unter Verwendung der Hauptkomponentenanalyse bzw. PCA und Erzeugen von PCA-Koeffizienten, die sowohl lineare als auch nichtlineare Änderungen in den individuellen Mustern anzeigen und
Bestimmen des Betrags der linearen und nichtlinearen Änderungen durch Verwendung des zeitveränderlichen Mittelwerts und der Varianz der PCA-Koeffizienten und Bestimmen der Komplexität der linearen und nichtlinearen Änderungen durch Berechnen der Anzahl der PCA-Koeffizienten, die im wesentlichen gleichzeitige Änderungen aufweisen.

4. Verfahren nach Anspruch 1, wobei das Analysieren in hoher Auflösung folgendes umfaßt:

Bilden von Zeitreihen aus den seriellen Änderungen;
Charakterisieren der Zeitreihen unter Verwendung der Hauptkomponentenanalyse bzw. PCA und Erzeugen von PCA-Koeffizienten, die sowohl lineare als auch nichtlineare Änderungen in dem individuellen Muster anzeigen;
Präsentieren der PCA-Koeffizienten als Vektor im n-dimensionalen Raum, wobei n die Anzahl der analysierten Variablen ist und
Bestimmen von Betrag und Richtung der kombinierten Änderungen in den charakteristischen Variablen durch die Änderungen von Betrag und Richtung des n-dimensionalen Vektors.

5. Verfahren nach Anspruch 1, bei dem der niedrige Auflösungsgrad ein Vergleichen der primären Elemente mit normalen Werten für solche primäre Elemente und das Repräsentieren der Abweichung primärer Elemente von den normalen Werten in einer für Laien verständlichen Form umfaßt.

6. Verfahren nach Anspruch 5, ferner mit dem Schritt des Repräsentierens von Abweichungen der primären Elemente von den normalen Werten in einer quantitativen Form zur Verwendung durch eine medizinische Fachkraft.

7. Verfahren nach Anspruch 1, mit dem Schritt des Ertönenlassens eines Alarms, wenn die niedrige Auflösung ein abnormes oder instabiles primäres Element detektiert.

8. Elektrokardiographisches bzw. EKG-System zur Detektion und Analyse serieller Änderungen in EKG-Daten in mindestens zwei Detaillierungsgraden, wobei das System folgendes umfaßt:

eine Beschaffungseinheit zum Sammeln von EKG-Signalen von einem Subjekt über einen Zeitraum von mindestens mehreren Sekunden;
eine erste Analyse- und Verarbeitungseinheit zum Detektieren mindestens eines von mehreren primären Elementen aus den EKG-Daten und zum Verarbeiten des mindestens einen mehrerer primärer Elemente (als Analyse mit niedriger Auflösung bezeichnet), um das mindestens eine von mehreren primären Elementen respektierende Daten zu erzeugen;
mindestens eine Speichereinheit zum Speichern mindestens eines Referenzwerts der mehreren primären Elemente;
eine vergleichende Einheit zum Vergleichen des mindestens einen Referenzwerts mit neu aus der ersten Ana-

lyse- und Verarbeitungseinheit empfangenen Daten und zum Produzieren mindestens eines Indikators von Unterschieden zwischen dem mindestens einen Referenzwert und den neu empfangenen Daten;
eine zweite Analyseeinheit zum Bewerten von Änderungen in seriellen EKG-Daten (als Analyse mit höherer Auflösung bezeichnet) und zum Charakterisieren von Zeitreihen mindestens eines primären elements oder Index in der Menge von primären elementen und Indizes in höherer Auflösung unter Verwendung mindestens eines Verfahrens, das aus mathematischer Zerlegung und Mustererkennung ausgewählt wird und
eine Kommunikationseinheit zum Austauschen von Informationen zwischen der Verarbeitung in niedriger Auflösung und der höheren Auflösung, so daß an der Verarbeitung Justierungen vorgenommen werden können.

9. EKG-System nach Anspruch 8, bei dem die erste Analyseeinheit Mittel zum Empfangen von Befehlen von der zweiten Analyseeinheit enthält, um die aus EKG-Signalen zu detektierenden primären Elemente zu justieren.

10. EKG-System nach Anspruch 8, das mindestens eine Ausgabeeinheit zur qualitativen Repräsentation mit mindestens einem statischen Bildschirm für einmalige EKG-Präsentation und einem dynamischen Bildschirm zum Präsentieren von Änderungen in seriellen EKG-Aufzeichnungen umfaßt.

11. EKG-System nach Anspruch 8, bei dem die Menge von primären Elementen mindestens einen Indikator umfaßt, der aus einer vollständigen Menge charakteristischer Fragmente der EKG-Signale und ihrer Parameter ausgewählt wird, wobei die Menge von charakteristischen Fragmenten P-, Q-, R-, S-, T- und U-Wellen, ST-Segment, PR-, QRS- und QT-Intervalle enthält, wobei die Parameter die Amplitude und Dauer der Wellen und Segmente und die Zeitintervalle zwischen den Herzschlägen enthalten.

12. EKG-System nach Anspruch 8, bei dem die Menge von primären Elementen die Amplituden der T-Welle und U-Welle zu einem einzigen Index für Patienten mit bekannten Elektrolytabnormitäten kombiniert enthält.

13. EKG-System nach Anspruch 9, bei dem die Ausgabeeinheit einen Bildschirm zum Anzeigen mindestens eines der qualitativen Indikatoren einer minimalen Menge signifikantester Indizes zur Anzeige eines im wesentlichen abnormen Zustands und einen Bildschirm zur quantitativen Repräsentation, der eine Menge von charakteristischen Fragmenten und ihre Parameter repräsentiert, enthält.

14. EKG-System nach Anspruch 8, bei dem die erste Analyse- und Verarbeitungseinheit Mittel zum Zerlegen der EKG-Signale in mehrere Elemente enthält und die Zerlegungsmittel eine orthogonale Zerlegung ausführen, um die signifikantesten Informationen aus den EKG-Signalen zu extrahieren.

15. EKG-System nach Anspruch 8, bei dem die erste Analyse- und Verarbeitungseinheit, die Speichereinheit und die vergleichende Einheit zu einer mit der Kommunikationseinheit verbundenen Einheit mit Taschengröße kombiniert sind.

16. EKG-System nach Anspruch 15, bei dem die Kommunikationseinheit drahtlos ist.

17. EKG-System nach Anspruch 15, bei dem die Speichereinheit Speicherung für einen physiologischen Bereich der primären Elemente und einen Detektor für Fehler und Rauschen zum Zurückweisen der Daten bei Detektion der primären Elemente oder der Indizes außerhalb des physiologischen Bereichs enthält.

18. EKG-System nach Anspruch 8, bei dem die Ausgabeeinheit ein Display zum Betrachten mindestens eines der EKG-Signale enthält.

19. System nach Anspruch 8, bei dem die Mittel zum Sammeln und Speichern eine Einheit mit Taschengröße mit drahtloser Kommunikation mit dem Rest des tragbaren Elektrokardiographen sind.

20. System nach Anspruch 8, bei dem die Menge von Referenzwerten charakteristische Werte für die Menge von primären Elementen und Indizes, die zuvor gespeichert wurden, oder vorgegebene charakteristische Werte umfaßt.

21. EKG-System nach Anspruch 8, bei dem die Mittel zum Repräsentieren ein LCD-Display zum Betrachten des EKG-Signals umfassen, wobei das LCD-Display einen Bereich normaler oder zuvor gespeicherter Werte für mehrere charakteristische Punkte und Segmente repräsentiert.

22. Vorrichtung zur Detektion und Analyse von EKG-Signalen und/oder physiologischen Signalen in mindestens zwei

Detaillierungsgraden (oder Auflösung) und zum Anzeigen von in den EKG-Signalen und/oder physiologischen Signalen detektierten Änderungen, wobei das System folgendes umfaßt:

eine Beschaffungseinheit zum Empfangen von durch Überwachen eines Subjekts für mindestens mehrere Sekunden erzeugten Signalen;
ein Analysemodul zum Detektieren mindestens eines von mehreren primären Elementen aus den Signalen, um einmalige Änderungen in dem mindestens einen von mehreren primären Elementen zu detektieren (als Analyse mit niedriger Auflösung bezeichnet) und **dadurch** etwaige abnorme oder instabile primäre Elemente zu identifizieren;
eine Speichereinheit zum Speichern mindestens eines Referenzwerts, der die mehreren primären Elemente respektiert;
eine vergleichende Einheit zum Vergleichen mindestens eines Referenzwerts aus der Speichereinheit mit mindestens einem von mehreren neu aus dem Analysemodul empfangenen primären Elementen und zum Produzieren von qualitativen Indikatoren und/oder quantitativen Indikatoren, die die Unterschiede in den Daten repräsentieren und
eine Kommunikationseinheit zum Austauschen von Daten mit einer Fernanalyse- und -vergleichseinheit für Analyse der Signale auf hoher Ebene, wobei die Fernanalyse- und -vergleichseinheit mindestens ein Verfahren verwendet, das aus mathematischer Zerlegung und Mustererkennung ausgewählt wird, um detaillierte Charakterisierung serieller Änderungen in den abnormen oder instabilen primären Elementen bereitzustellen, wobei die Analyseeinheit Mittel zum Empfangen von Befehlen von der Fernanalyse- und -vergleichseinheit zum Umprogrammieren der Analyseeinheiten enthält.

23. Vorrichtung nach Anspruch 22, bei der das Analysemodul und die vergleichende Einheit Daten in mindestens drei Detaillierungsgraden analysieren und vergleichen.

24. Vorrichtung nach Anspruch 23, bei der das Analysemodul Mittel zum Verwenden der Befehle aus der Fernanalyseeinheit enthält, um die aus den Signalen zu detektierenden primären Elemente zu modifizieren.

25. Vorrichtung nach Anspruch 22, die aus den seriellen Änderungen eine Zeitreihe bildet, die Zeitreihe unter Verwendung von für Hauptkomponentenanalyse bzw. PCA ausgelegter methematischer Zerlegung charakterisiert und PCA-Koeffizienten erzeugt, die sowohl lineare als auch nichtlineare Änderungen in dem individuellen Muster anzeigen, den Betrag der linearen und nichtlinearen Änderungen durch Verwendung des zeitveränderlichen Mittelwerts unter Varianz der PCA-Koeffizienten bestimmt und die Komplexität der linearen und nichtlinearen Änderungen durch Berechnen der Anzahl der PCA-Koeffizienten, die im wesentlichen gleichzeitige Änderungen aufweisen, bestimmt.

26. Verfahren nach Anspruch 1, bei dem das Analysieren in hoher Auflösung folgendes umfaßt:

Bilden einer Zeitreihe aus den seriellen Änderungen;
Charakterisieren der Zeitreihe unter Verwendung einer für Hauptkomponentenanalyse bzw. PCA ausgelegten mathematischen Zerlegung und Erzeugen von Eigenvektoren und Eigenwerten, die sowohl lineare als auch nichtlineare Änderungen in dem individuellen Muster anzeigen und
Bestimmen von Betrag und Komplexität der linearen und nichtlinearen Änderungen durch Vergleichen der entsprechenden Eigenvektoren und Eigenwerte.

27. EKG-System nach Anspruch 8, bei dem die Mittel zum Charakterisieren der Zeitreihe mindestens eines primären Elements oder Index auch Eigenvektoren und Eigenwerte erzeugen.

28. EKG-System nach Anspruch 8, bei dem der mindestens eine Referenzwert aus normalen Werten, Daten eines Individuums, durch die erste Analyse- und -verarbeitungseinheit erzeugten primären Elementen, durch die zweite Analyseeinheit erzeugten Werten, manuell editierten Referenzwerten, programmierten Referenzwerten, Vorgabe-Referenzwerten und Reihen vorheriger erhaltener Werte ausgewählt wird.

29. EKG-System nach Anspruch 8, das für mindestens eine der folgenden Umgebungen implementiert ist, die aus einmaligen Untersuchungen durch Patienten, medizinische Fachkräfte, Sanitäter und Laien der Öffentlichkeit für dynamische Bewertung von Änderungen in elektrischer Herzaktivität, Erste-Hilfe-EKG-Analyse für Notfalleinheiten, Sanitäter und medizinisches Personal, für eine routinemäßige medizinische Untersuchung, eine persönliche einmalige oder serielle EKG-Analyse mit Speicherung individueller elektrokardiographischer Vorgeschichtedaten, adaptive Justierung individueller Schwellen und Bewertung von Änderungen in einem individuellen EKG-Muster, eine

einmalige oder serielle EKG-Analyse für eine Gruppe von Personen, eine Familie oder eine Patientengruppe mit Speicherung individueller elektrokardiographischer Vorgeschichtedaten für jede Person, Justierung individueller Schwellen und Bewertung von Änderungen in individuellen EKG-Mustern, Ereignisüberwachung, Verfolgung von Änderungen der Herzschlagrate oder des ST-Segments, Arrhythmie, Bett-, Belastungsprüfungsüberwachung, Prüfung von Herzschrittmachern und anderen implantierbaren Einrichtungen, Bewertung der Behandlungswirksamkeit, Nebenwirkungen und des Fortschritts der Krankheit ausgewählt werden.

30. EKG-System nach Anspruch 8, das mindestens eine der Komponenten enthält, die aus einer Datenbank ausgewählt werden, die die Signifikanz der Änderungen in jedem primären Element erläutert, wobei einfache Empfehlungen über die zu unternehmenden Maßnahmen gegeben werden, wenn die Meßwerte der Indikatoren abnorm werden, einschließlich einer vollständigen Beendigung physischer Aktivität, Kontaktieren einer medizinischen Fachkraft, Einnehmen einer Medikation, detaillierterer Empfehlungen für Patienten mit spezifischen Abnormitäten oder Medikationen, spezieller Überwachung, individueller Justierung der primären Elemente für Patienten mit spezifischen Abnormitäten oder Medikationen, Überwachung der Dauer des QT-Intervalls.

31. Verfahren nach Anspruch 1, bei dem die Analyse für einmalige Untersuchungen durch Patienten und/oder medizinische Fachkräfte und/oder Sanitäter und Laien der Öffentlichkeit und/oder für dynamische Bewertung von Änderungen der elektrischen Herzaktivität und/oder Erste-Hilfe-EKG-Analyse für Notfalleinheiten und/oder Sanitäter und/oder medizinisches Personal und/oder für eine routinemäßige medizinische Untersuchung und/oder eine persönliche einmalige oder serielle EKG-Analyse mit Speicherung individueller elektrokardiographischer Vorgeschichtedaten und/oder adaptive Justierung individueller Schwellen und Bewertung von Änderungen in individuellen EKG-Mustern und/oder einmalige oder serielle EKG-Analyse für eine Gruppe von Personen, eine Familie oder eine Patientengruppe mit Speicherung individueller elektrokardiographischer Vorgeschichtedaten für jede Person und/oder Justierung individueller Schwellen und Bewertung von Änderungen in individuellen EKG-Mustern und/oder Ereignisüberwachung und/oder Verfolgung von Änderungen der Herzschlagrate oder des ST-Segments und/oder Arrhythmie und/oder Bett-, Belastungsprüfungsüberwachung und/oder Prüfung von Herzschrittmachern und anderen implantierbaren Einrichtungen und/oder Bewertung der Behandlungswirksamkeit, Nebenwirkungen und des Fortschritts der Krankheit angewandt wird.

32. EKG-System nach Anspruch 8, bei dem die Erfassungseinheit und/oder eine erste Analyse- und -verarbeitungseinheit und/oder eine Speichereinheit und/oder eine vergleichende Einheit und/oder eine Kommunikationseinheit und/oder eine zweite Analyseeinheit unter Verwendung eines spezialisierten Prozessors und/oder eines Personal Computers und/oder eines Computer-Organizers implementiert werden.

33. Vorrichtung nach Anspruch 22, bei der die Erfassungseinheit und/oder eine Analyseeinheit und/oder eine Speichereinheit und/oder eine vergleichende Einheit und/oder eine Ausgabeeinheit und/oder eine Kommunikationseinheit und/oder eine Fernverarbeitungseinheit unter Verwendung eines spezialisierten Prozessors und/oder eines Personal Computers und/oder eines Computer-Organizers implementiert werden.

34. EKG-System nach Anspruch 32, bei dem mindestens eine der Ausgabeeinheiten Abweichungen von primären Elementen von Referenzwerten unter Verwendung mindestens einer farbcodierten Skala oder symbolcodierten Skala repräsentiert.

35. Vorrichtung nach Anspruch 33, bei der mindestens eine der Ausgabeeinheiten Abweichungen von primären Elementen von Referenzwerten unter Verwendung mindestens einer farbcodierten Skala oder symbolcodierten Skala repräsentiert.

36. EKG-System nach Anspruch 8, bei dem die Verarbeitung und detaillierte Analyse serieller Änderungen unter Verwendung eines leistungsstarken Prozessors und/oder eines Netzwerks von Computern und/oder des Internets implementiert wird.

37. Vorrichtung nach Anspruch 22, bei der die Verarbeitung und detaillierte Analyse serieller Änderungen unter Verwendung eines leistungsstarken Prozessors und/oder eines Netzwerks von Computern und/oder des Internets implementiert wird.

Revendications

1. Procédé d'analyse dynamique de données électrocardiographiques (ECG) selon au moins deux niveaux de détail, ledit procédé comprenant :

   le recueil de signaux ECG provenant d'un sujet,
   l'analyse d'un nombre limité d'éléments primaires dans lesdites données ECG (appelée une analyse à faible résolution) et la comparaison desdits éléments primaires à au moins une valeur de référence afin de détecter des modifications à un instant dans de tels éléments primaires et identifier de ce fait des éléments primaires anormaux ou instables,
   l'analyse de modifications en série dans lesdites données ECG (appelée une analyse à haute résolution) en utilisant au moins un procédé sélectionné à partir d'une décomposition mathématique et d'une reconnaissance de séquence pour fournir la caractérisation de modifications en série dans lesdits éléments primaires anormaux ou instables,
   l'échange d'informations entre ladite analyse à faible résolution et ladite analyse à haute résolution, et
   l'ajustement de ladite analyse sur la base de ladite caractérisation de modifications en série dans les éléments primaires.

2. Procédé selon la revendication 1, dans lequel ladite analyse à haute résolution inclut en outre :

   la combinaison d'une pluralité desdites modifications en série dans les éléments primaires anormaux ou instables et l'analyse des modifications combinées en utilisant une décomposition mathématique, et
   la sélection d'une combinaison de paramètres permettant de suivre les modifications desdits éléments anormaux ou instables et l'envoi d'informations respectant la combinaison sélectionnée vers ladite analyse à basse résolution en vue d'un ajustement de paramètres de surveillance.

3. Procédé selon la revendication 1, dans lequel ladite analyse à haute résolution comprend :

   la formation d'une série dans le temps à partir desdites modifications en série,
   la caractérisation de ladite série dans le temps en utilisant l'Analyse en Composant Principal (ACP) et la génération de coefficients ACP indicatifs à la fois des modifications linéaires et non linéaires dans la séquence individuelle, et
   la détermination de l'amplitude desdites modifications linéaires et non linéaires en utilisant une moyenne et une variance variant dans le temps desdits coefficients ACP, ainsi qu'en déterminant la complexité desdites modifications linéaires et non linéaires en calculant le nombre de coefficients ACP qui présentent des modifications sensiblement simultanées.

4. Procédé selon la revendication 1, dans lequel ladite analyse à haute résolution comprend :

   la formation de séries dans le temps à partir desdites modifications en série, la caractérisation desdites séries dans le temps en utilisant l'Analyse en Composant Principal (ACP) et la génération de coefficients ACP indiquant à la fois les modifications linéaires et non linéaires dans la séquence individuelle,
   la présentation desdits coefficients ACP sous forme d'un vecteur dans l'espace à n dimensions, où n représente le nombre de variables analysées, et
   la détermination de l'amplitude et de la direction des modifications combinées dans les variables caractéristiques grâce à des modifications d'amplitude et de direction dudit vecteur à n dimensions.

5. Procédé selon la revendication 1, dans lequel ladite faible résolution inclut la comparaison desdits éléments primaires à des valeurs normales de tels éléments primaires, ainsi que la représentation de l'écart des éléments primaires par rapport aux valeurs normales sous une forme compréhensible à une personne profane.

6. Procédé selon la revendication 5 qui comprend en outre la représentation des écarts desdits éléments primaires par rapport auxdites valeurs normales sous une forme quantitative en vue d'une utilisation par un professionnel de la médecine.

7. Procédé selon la revendication 1, qui inclut le fait de faire résonner une alarme lorsque ladite faible résolution détecte un élément primaire anormal ou instable.

8. Système électrocardiographique ECG en vue de la détection et de l'analyse de modifications en série de données ECG selon au moins deux niveaux de détail, ledit système comprenant :

une unité d'acquisition permettant de recueillir des signaux ECG provenant d'un sujet sur une certaine période d'au moins plusieurs secondes,
une première unité d'analyse et de traitement permettant de détecter au moins l'un élément d'une pluralité d'éléments primaires provenant desdites données ECG et de traiter ledit ou lesdits éléments d'une pluralité d'éléments primaires (ce que l'on appelle une analyse à faible résolution) afin de générer des données respectant ledit ou lesdits éléments d'une pluralité d'éléments primaires,
au moins une unité de mémorisation permettant de mémoriser au moins une valeur de référence de ladite pluralité d'éléments primaires,
une unité de comparaison permettant de comparer ladite ou lesdites valeurs de référence à des données venant d'être reçues de ladite première unité d'analyse et de traitement et de constituer au moins un indicateur de différences entre ladite ou lesdites valeurs de référence et lesdites données qui viennent d'être reçues,
une seconde unité d'analyse permettant d'évaluer des modifications dans les données ECG en série (appelée une analyse à haute résolution) et de caractériser des séries dans le temps d'au moins un élément ou index primaire dans ledit jeu d'éléments ou d'index primaires avec une résolution plus élevée en utilisant au moins un procédé sélectionné à partir d'une décomposition mathématique et d'une reconnaissance de séquence, et
une unité de communications permettant d'échanger des informations entre ledit traitement à faible résolution et ladite résolution plus élevée de telle sorte que des ajustements puissent être réalisés dans ledit traitement.

9. Système ECG selon la revendication 8, dans lequel ladite première unité d'analyse inclut un moyen permettant de recevoir des instructions provenant de ladite seconde unité d'analyse afin d'ajuster les éléments primaires à détecter à partir de signaux ECG.

10. Système ECG selon la revendication 8 qui inclut au moins une unité de sortie fournissant une représentation qualitative incluant au moins un écran statique destiné à une présentation à un instant d'un ECG et un écran dynamique permettant de présenter des modifications dans les enregistrements d'ECG en série.

11. Système ECG selon la revendication 8, dans lequel ledit jeu d'éléments primaires inclut au moins un indicateur sélectionné à partir d'un jeu complet de fragments caractéristiques des signaux ECG et de leur paramètres, ledit jeu de fragments caractéristiques incluant les ondes P, Q, R, S, T, et U, un segment ST, des intervalles PR, QRS et QT, lesdits paramètres incluant l'amplitude et la durée desdites ondes et desdits segments, ainsi que les intervalles de temps entre les battements de coeur.

12. Système ECG selon la revendication 8, dans lequel ledit jeu d'éléments primaires inclut les amplitudes des ondes T et U combinées en un seul index pour des patients présentant des anomalies connues d'électrolyte.

13. Système ECG selon la revendication 9, dans lequel ladite unité de sortie inclut un écran permettant d'afficher au moins l'un desdits indicateurs qualitatifs d'un jeu minimal des index les plus significatifs afin d'indiquer un état sensiblement anormal, ainsi qu'un écran destiné à une représentation quantitative qui représente un jeu de fragments caractéristiques et de leurs paramètres.

14. Système ECG selon la revendication 8, dans lequel ladite première unité d'analyse et de traitement inclut un moyen permettant de décomposer les signaux ECG en une pluralité d'éléments, et dans lequel ledit moyen de décomposition effectue une décomposition orthogonale destinée à extraire les informations les plus significatives sur les signaux ECG.

15. Système ECG selon la revendication 8, dans lequel ladite première unité d'analyse et de traitement, l'unité de mémorisation et l'unité de comparaison sont combinées en une seule unité tenant dans une poche reliée à ladite unité de communications.

16. Système ECG selon la revendication 15, dans lequel ladite unité de communications est sans fil.

17. Système ECG selon la revendication 15, dans lequel ladite unité de mémorisation inclut une mémorisation destinée à une plage physiologique des éléments primaires et un détecteur d'erreur et de bruit permettant de rejeter les données lors de la détection d'éléments primaires ou d'index se trouvant au-delà de la plage physiologique.

18. Système ECG selon la revendication 8, dans lequel ladite unité de sortie inclut un afficheur permettant de visualiser au moins l'un des signaux ECG.

19. Système selon la revendication 8, dans lequel ledit moyen permettant d'effectuer un recueil et une mémorisation est une unité tenant dans une poche ayant une communication sans fil avec le reste de l'électrocardiographe portatif.

20. Système selon la revendication 8, dans lequel ledit jeu de valeurs de référence inclut des valeurs caractéristiques pour ledit jeu d'éléments primaires et d'index précédemment mémorisés, ou bien des valeurs caractéristiques par défaut.

21. Système ECG selon la revendication 8, dans lequel ledit moyen permettant d'effectuer une représentation inclut un afficheur LCD permettant de visualiser le signal ECG, ledit afficheur LCD représentant une plage de valeurs normales ou mémorisées précédemment pour une pluralité de points et de segments caractéristiques.

22. Appareil pour la détection et l'analyse d'au moins l'un parmi des signaux ECG et des signaux physiologiques selon au moins deux niveaux de détail (ou de résolution) et affichant des modifications détectées dans ledit au moins un parmi des signaux ECG et des signaux physiologiques, ledit système comprenant :

une unité d'acquisition permettant de recevoir des signaux générés en surveillant un sujet pendant au moins plusieurs secondes,
un module d'analyse permettant de détecter au moins un élément d'une pluralité d'éléments primaires à partir desdits signaux afin de détecter des modifications à un instant dans ledit ou lesdits éléments d'une pluralité d'éléments primaires (ce qu'on appelle une analyse à faible résolution) et d'identifier de ce fait tous les éléments primaires anormaux ou instables,
une unité de mémorisation permettant de mémoriser au moins une valeur de référence respectant ladite pluralité d'éléments primaires,
une unité de comparaison permettant de comparer ladite ou lesdites valeurs de référence depuis ladite unité de mémorisation à au moins l'un d'une pluralité d'éléments primaires venant juste d'être reçus dudit module d'analyse, et de produire au moins l'un des indicateurs qualitatifs et des indicateurs quantitatifs représentant les différences dans les données, et
une unité de communications permettant d'échanger des données avec une unité d'analyse et de comparaison à distance en vue d'une analyse à haut niveau desdits signaux, ladite unité d'analyse et de comparaison à distance utilisant au moins un procédé sélectionné à partir d'une décomposition mathématique et d'une reconnaissance de séquence en vue de procurer une caractérisation détaillée des modifications en série dans lesdits éléments primaires anormaux ou instables et ladite unité d'analyse incluant un moyen permettant de recevoir des instructions de ladite unité d'analyse et de comparaison à distance afin de reprogrammer lesdites unités d'analyse.

23. Appareil selon la revendication 22, dans lequel ledit module d'analyse et ladite unité de comparaison analysent et comparent des données selon au moins trois niveaux de détail.

24. Appareil selon la revendication 23, dans lequel ledit module d'analyse inclut un moyen permettant d'utiliser lesdites instructions provenant de ladite unité d'analyse à distance pour modifier les éléments primaires à détecter à partir desdits signaux.

25. Appareil selon la revendication 22 qui forme une série dans le temps à partir desdites modifications en série, qui caractérise lesdites séries dans le temps en utilisant une décomposition mathématique conçue pour une Analyse en Composant Principal (ACP) et qui génère des coefficients ACP indicatifs à la fois des modifications linéaires et non linéaires dans la séquence individuelle, qui détermine l'amplitude desdites modifications linéaires et non linéaires en utilisant une moyenne et une variance variant dans le temps desdits coefficients ACP et qui détermine la complexité desdites modifications linéaires et non linéaires en calculant le nombre de coefficients ACP qui présentent des modifications sensiblement simultanées.

26. Procédé selon la revendication 1, dans lequel ladite analyse à haute résolution comprend :

la formation d'une série dans le temps à partir desdites modifications en série,
la caractérisation de ladite série dans le temps en utilisant une décomposition mathématique conçue pour une Analyse en Composant Principal (ACP) et générant des vecteurs propres et des valeurs propres indicatifs à la

fois les modifications linéaires et non linéaires dans la séquence individuelle, et
la détermination de l'amplitude et de la complexité desdites modifications linéaires et non linéaires en comparant les vecteurs propres et les valeurs propres correspondants.

27. Système ECG selon la revendication 8, dans lequel ledit moyen permettant de caractériser des séries dans le temps d'au moins un élément ou index primaire génère également des vecteurs propres et des valeurs propres.

28. Système ECG selon la revendication 8, dans lequel ladite ou lesdites valeurs de référence sont sélectionnées à partir de valeurs normales, de données de l'individu, d'éléments primaires générés par ladite première unité d'analyse et de traitement, de valeurs générées par la seconde unité d'analyse, de valeurs de référence éditées manuellement, de valeurs de référence programmées, de valeurs de référence par défaut et de séries de valeurs obtenues précédemment.

29. Système ECG selon la revendication 8, lequel est mis en oeuvre pour au moins l'un des réglages suivants sélectionnés à partir d'examens à un instant par des patients, des professionnels de la médecine, des spécialistes paramédicaux et le public profane, en vue d'une évaluation dynamique de modifications de l'activité électrique cardiaque, de l'analyse ECG de premiers soins pour des unités d'urgence, des spécialistes paramédicaux et du personnel médical, pour un examen médical de routine, une analyse ECG à un instant ou de série d'une personne avec une mémorisation des données historiques électrocardiographiques individuelles, un ajustement adaptatif de seuils individuels et une évaluation de modifications dans une séquence ECG individuelle, une analyse ECG à un instant ou de série pour un groupe de personnes, une famille ou un groupe de patients, avec une mémorisation des données historiques électrocardiographiques individuelles pour chaque personne, un ajustement de seuils individuels et une évaluation de modifications de séquences ECG individuelles, une surveillance d'événements, le suivi de modifications du débit cardiaque ou du segment ST, une arythmie, une surveillance individuelle, une surveillance concernant une épreuve d'effort, un stimulateur cardiaque et autre contrôle par dispositif implantable, une évaluation de l'efficacité d'un traitement, d'effets collatéraux et de progression de la maladie.

30. Système ECG selon la revendication 8 qui inclut au moins l'un des composants sélectionnés à partir d'une base de données fournissant des explications sur la signification des modifications de chaque élément primaire, fournissant de simples recommandations sur les mesures qui doivent être prises si les lectures des indicateurs deviennent anormales, y compris l'arrêt complet d'une activité physique, la prise de contact d'un professionnel de la médecine, la prise de médicaments, des recommandations plus détaillées pour des patients qui présentent des anomalies ou des médications spécifiques, une surveillance spéciale, un ajustement individuel des éléments primaires pour des patients comportant des anomalies ou des médications spécifiques, la surveillance de la durée de l'intervalle QT.

31. Procédé selon la revendication 1, dans lequel l'analyse est appliquée pour au moins l'un des examens à un instant par des patients, des professionnels de la médecine, des spécialistes paramédicaux et le public profane, en vue d'une évaluation dynamique de modifications de l'activité électrique cardiaque, d'une analyse ECG de premiers soins pour des unités d'urgence, des spécialistes paramédicaux et du personnel médical, pour un examen médical de routine, une analyse ECG à un instant ou de série d'une personne avec une mémorisation des données historiques électrocardiographiques individuelles, un ajustement adaptatif de seuils individuels et une évaluation de modifications dans une séquence ECG individuelle, une analyse ECG à un instant ou de série pour un groupe de personnes, une famille ou un groupe de patients, avec une mémorisation des données historiques électrocardiographiques individuelles pour chaque personne, un ajustement de seuils individuels et une évaluation de modifications de séquences ECG individuelles, une surveillance d'événements, le suivi de modifications du débit cardiaque ou du segment ST, une arythmie, une surveillance individuelle, une surveillance concernant une épreuve d'effort, un stimulateur cardiaque et autre contrôle par dispositif implantable, une évaluation de l'efficacité d'un traitement, d'effets collatéraux et de progression de la maladie.

32. Système ECG selon la revendication 8, dans lequel au moins l'une de ladite unité d'acquisition, d'une première unité d'analyse et de traitement, d'une unité de mémorisation, d'une unité de comparaison, d'une unité de communications et d'une seconde unité d'analyse est mise en oeuvre en utilisant au moins l'un d'un processeur spécialisé, d'un ordinateur personnel et d'un organiseur informatique.

33. Appareil selon la revendication 22, dans lequel au moins l'une de ladite unité d'acquisition, d'une unité d'analyse, d'une unité de mémorisation, d'une unité de comparaison, d'une unité de sortie, d'une unité de communications et d'une unité de traitement à distance est mise en oeuvre en utilisant au moins l'un d'un processeur spécialisé, d'un ordinateur personnel et d'un organiseur informatique.

34. Système ECG selon la revendication 32, dans lequel au moins l'une desdites unités de sortie représente des écarts d'éléments primaires par rapport à des valeurs de référence en utilisant au moins une échelle codée par des couleurs ou une échelle codée par des symboles.

35. Appareil selon la revendication 33, dans lequel au moins l'une desdites unités de sortie représente des écarts d'éléments primaires par rapport à des valeurs de référence en utilisant au moins une échelle codée par des couleurs ou une échelle codée par des symboles.

36. Système ECG selon la revendication 8, dans lequel ledit traitement et analyse détaillée de modifications en série est mis en oeuvre en utilisant au moins l'un d'un processeur puissant, d'un réseau d'ordinateurs et du réseau Internet.

37. Appareil selon la revendication 22, dans lequel ledit traitement et analyse détaillée de modifications en série est mis en oeuvre en utilisant au moins l'un d'un processeur puissant, d'un réseau d'ordinateurs et du réseau Internet.

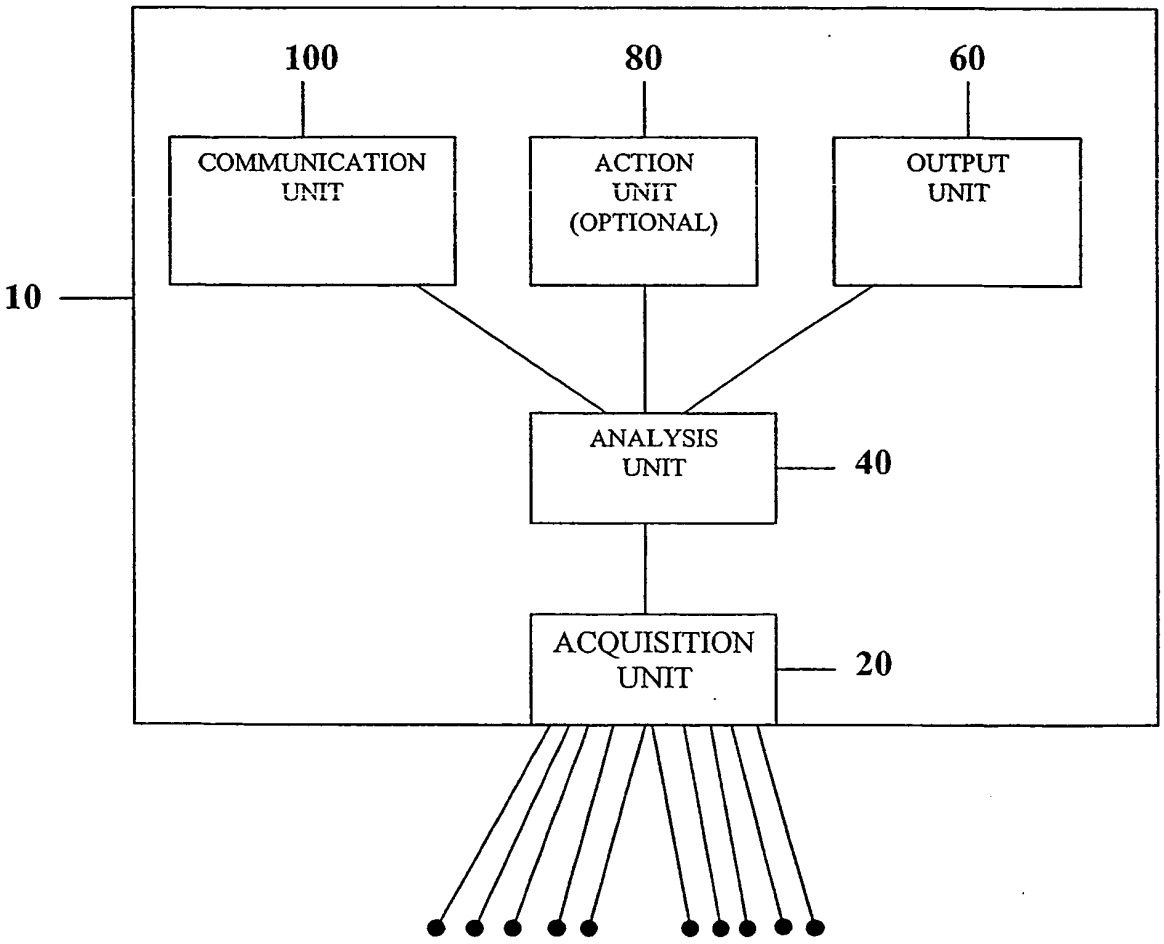
100
80
60
COMMUNICATION UNIT
ACTION UNIT (OPTIONAL)
OUTPUT UNIT
10
ANALYSIS UNIT
40
ACQUISITION UNIT
20

FIG. 1

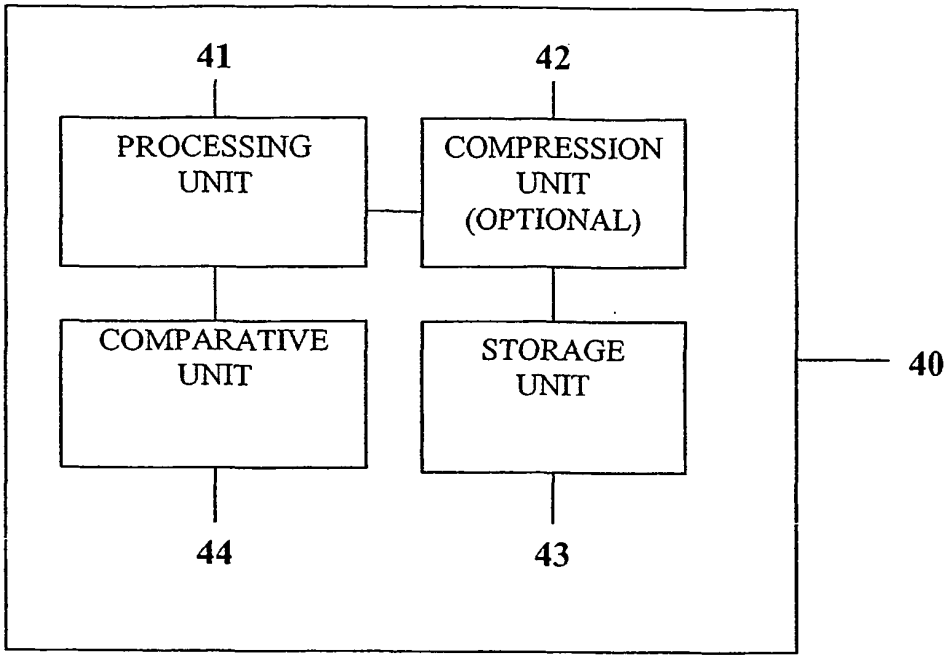
41
42
PROCESSING UNIT
COMPRESSION UNIT (OPTIONAL)
COMPARATIVE UNIT
STORAGE UNIT
40
44
43

FIG. 2

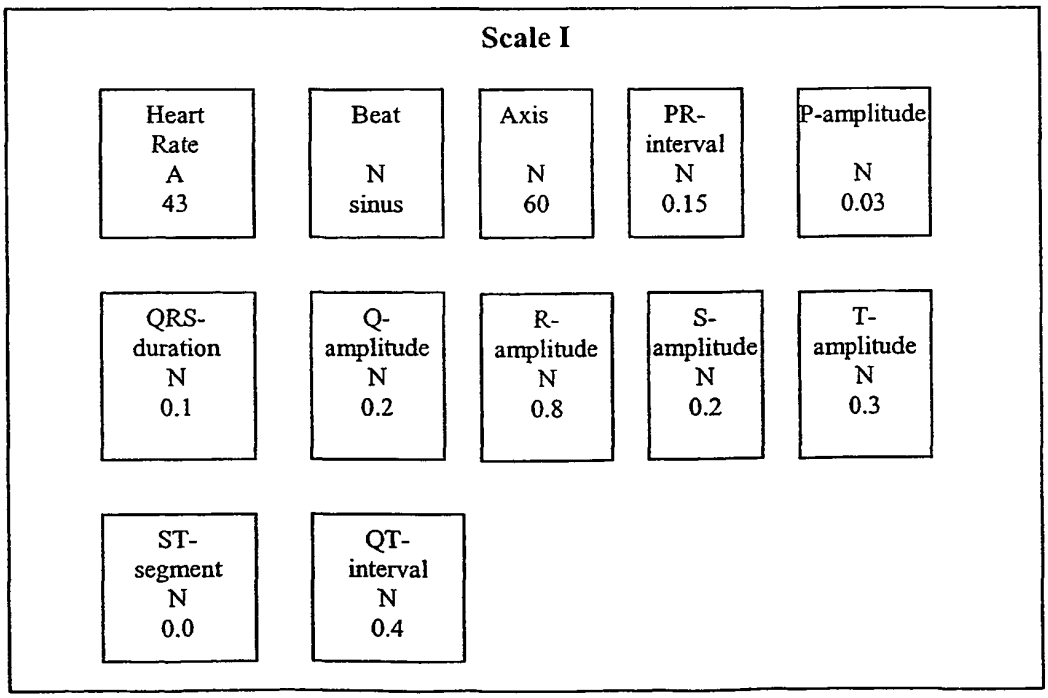
Scale I
Heart Rate A 43
Beat N sinus
Axis N 60
PR-interval N 0.15
P-amplitude N 0.03
QRS-duration N 0.1
Q-amplitude N 0.2
R-amplitude N 0.8
S-amplitude N 0.2
T-amplitude N 0.3
ST-segment N 0.0
QT-interval N 0.4

FIG. 3

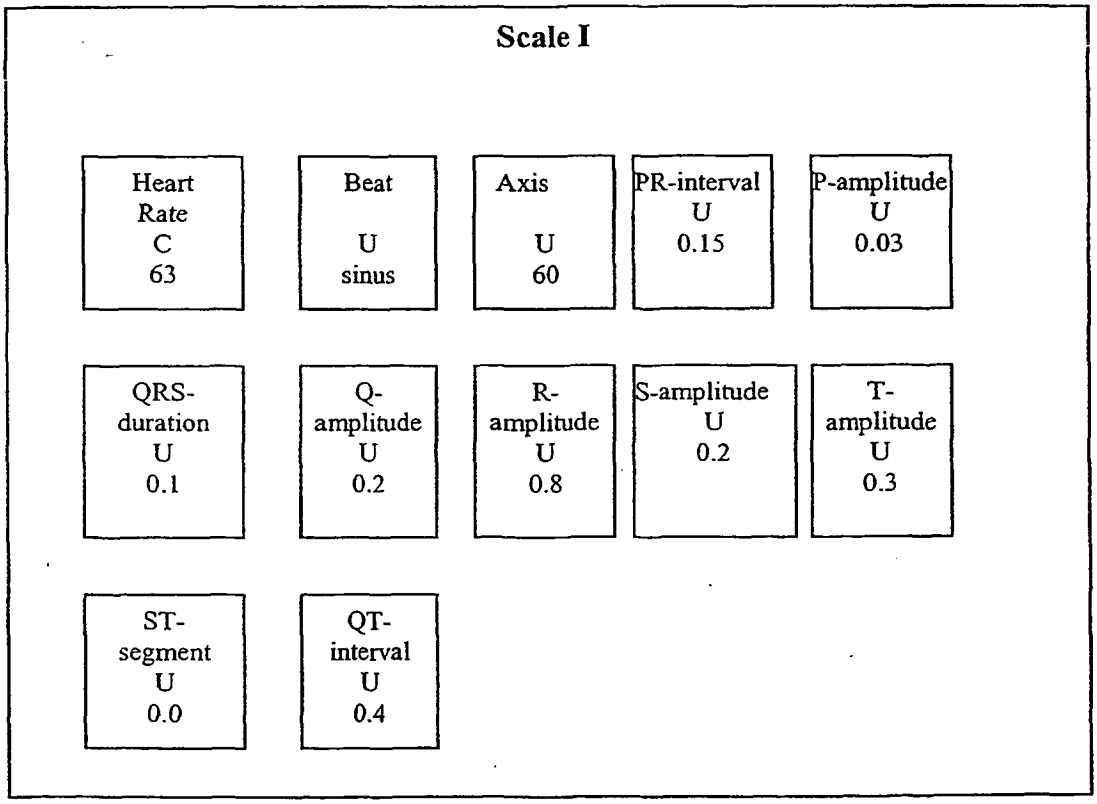
Scale I
Heart Rate C 63
Beat U sinus
Axis U 60
PR-interval U 0.15
P-amplitude U 0.03
QRS-duration U 0.1
Q-amplitude U 0.2
R-amplitude U 0.8
S-amplitude U 0.2
T-amplitude U 0.3
ST-segment U 0.0
QT-interval U 0.4

FIG. 4

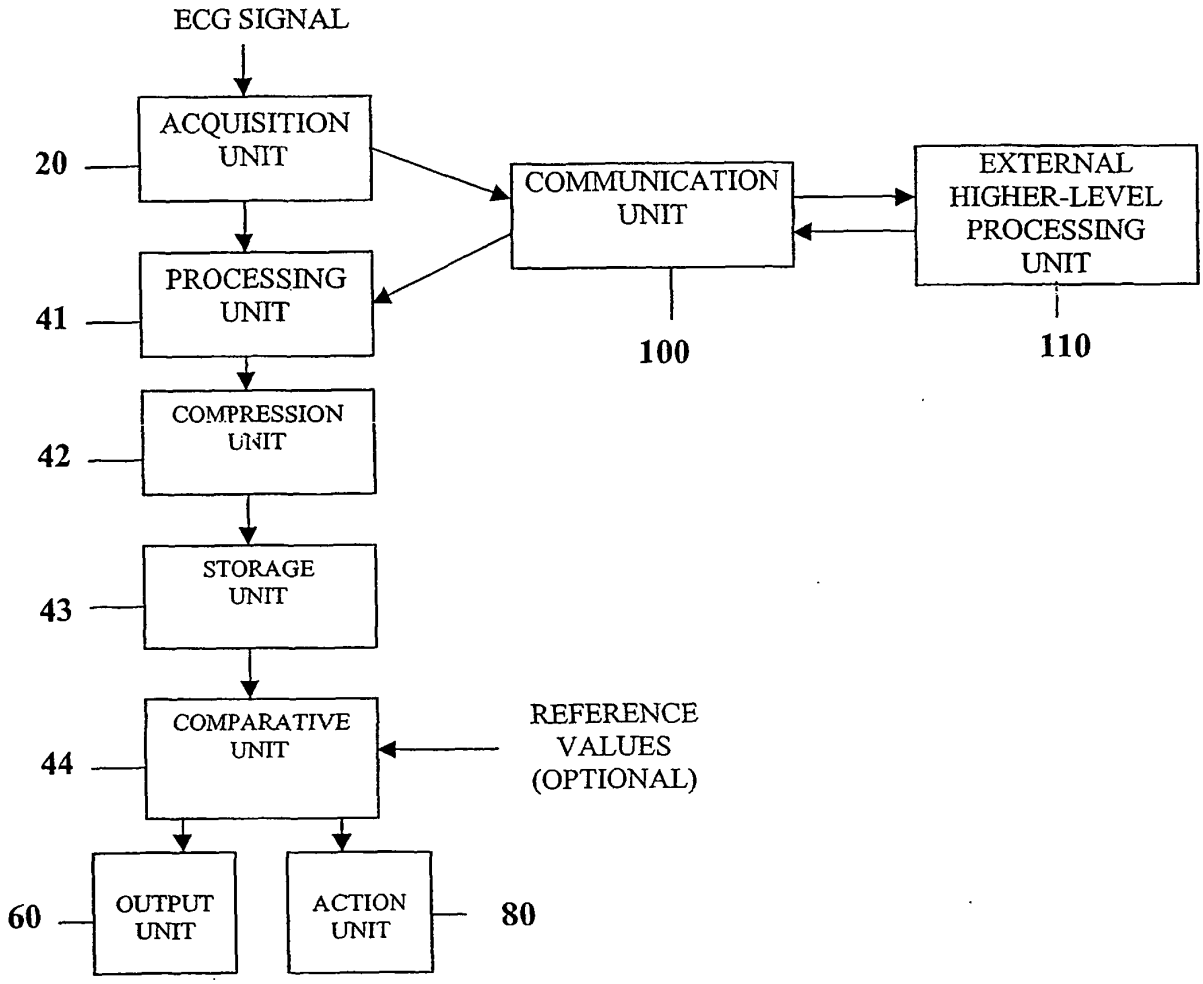
ECG SIGNAL
ACQUISITION UNIT
20
PROCESSING UNIT
41
COMPRESSION UNIT
42
STORAGE UNIT
43
COMPARATIVE UNIT
44
REFERENCE VALUES (OPTIONAL)
OUTPUT UNIT
60
ACTION UNIT
80
COMMUNICATION UNIT
100
EXTERNAL HIGHER-LEVEL PROCESSING UNIT
110

FIG. 5

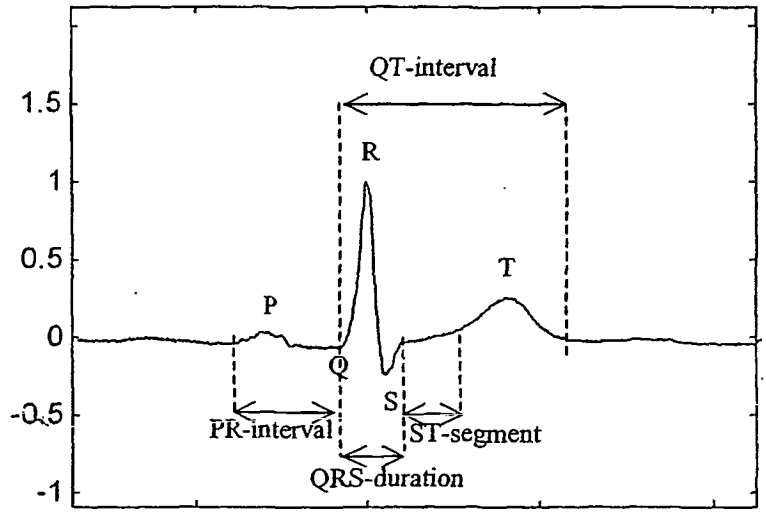
QT-interval
R
T
P
Q
S
PR-interval
ST-segment
QRS-duration
1.5
1
0.5
0
-0.5
-1

FIG. 6

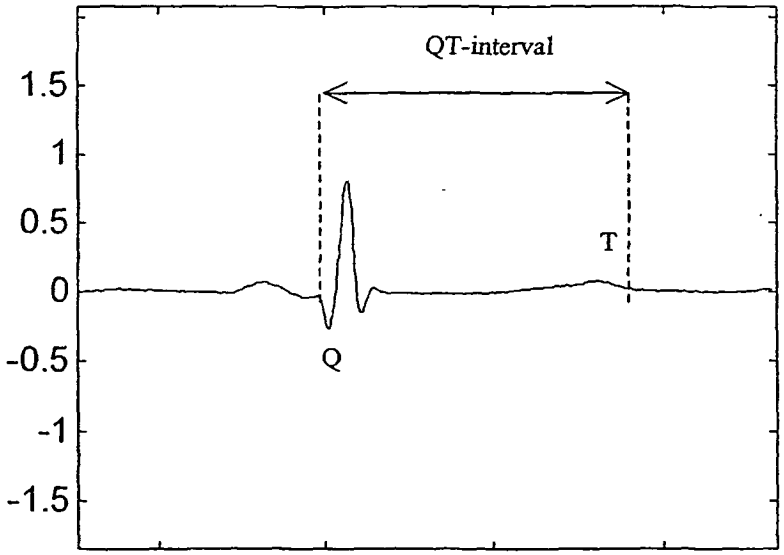
QT-interval
T
Q
1.5
1
0.5
0
-0.5
-1
-1.5

FIG. 7

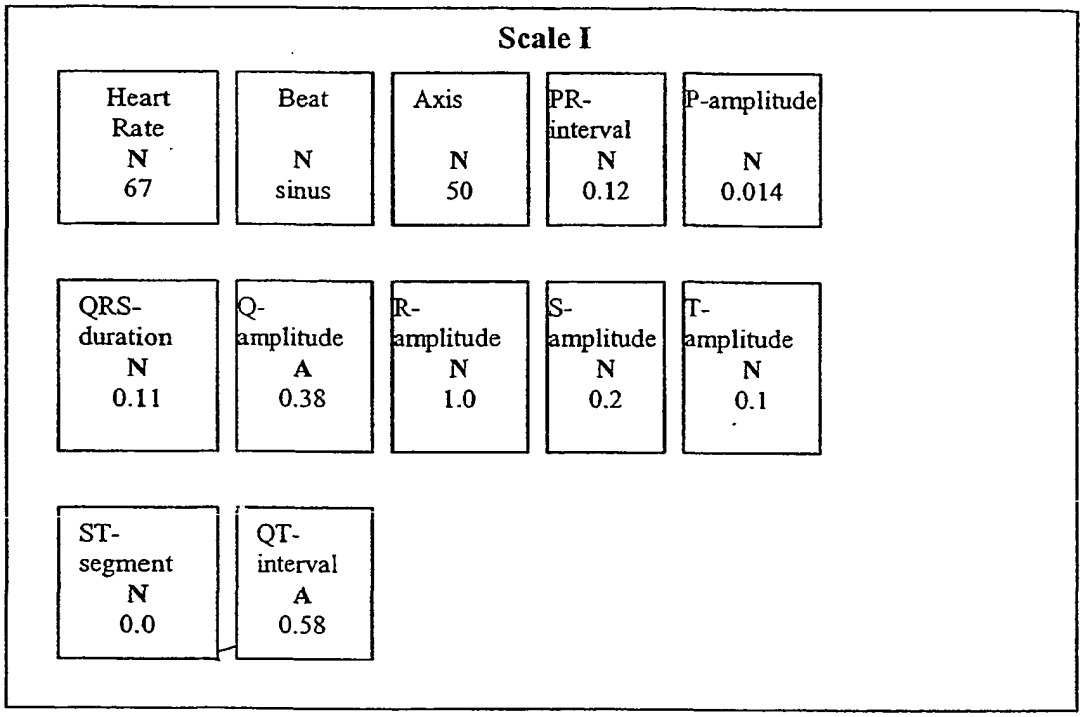
Scale I
Heart Rate N 67
Beat N sinus
Axis N 50
PR-interval N 0.12
P-amplitude N 0.014
QRS-duration N 0.11
Q-amplitude A 0.38
R-amplitude N 1.0
S-amplitude N 0.2
T-amplitude N 0.1
ST-segment N 0.0
QT-interval A 0.58

FIG. 8

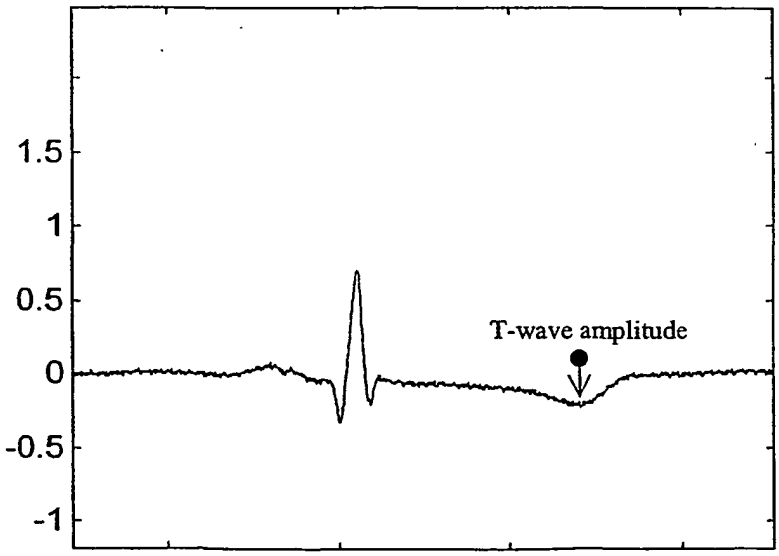
1.5
1
0.5
0
-0.5
-1
T-wave amplitude

FIG.9

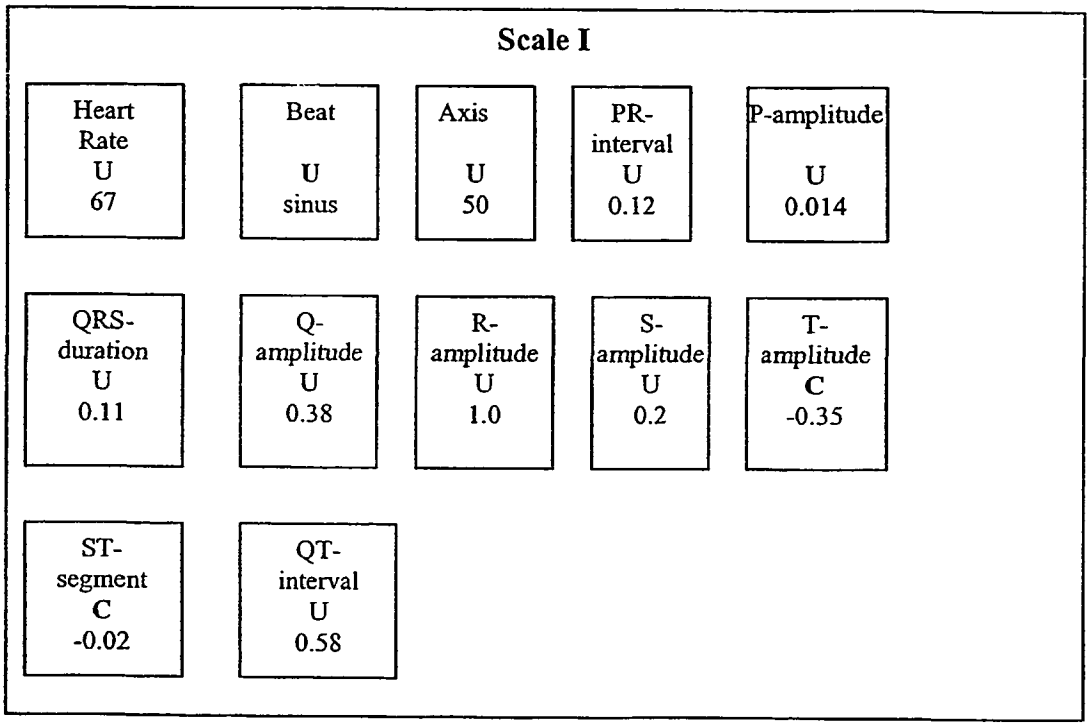
Scale I
Heart Rate U 67
Beat U sinus
Axis U 50
PR-interval U 0.12
P-amplitude U 0.014
QRS-duration U 0.11
Q-amplitude U 0.38
R-amplitude U 1.0
S-amplitude U 0.2
T-amplitude C -0.35
ST-segment C -0.02
QT-interval U 0.58

FIG. 10

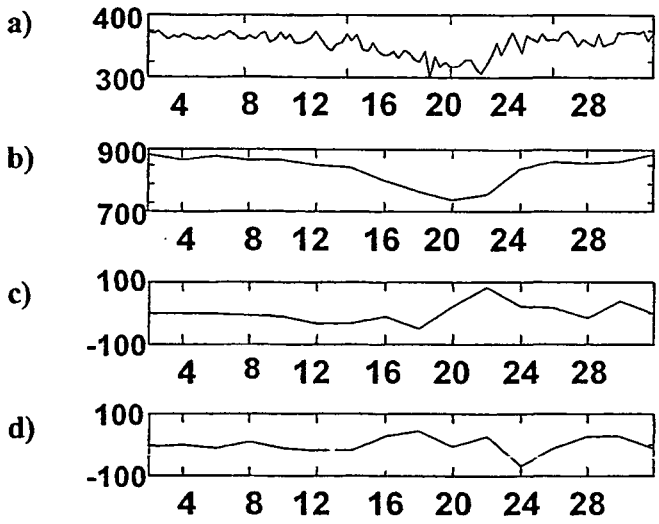
a)
400
300
4 8 12 16 20 24 28
b)
900
700
4 8 12 16 20 24 28
c)
100
-100
4 8 12 16 20 24 28
d)
100
-100
4 8 12 16 20 24 28
Time [days]

FIG. 11

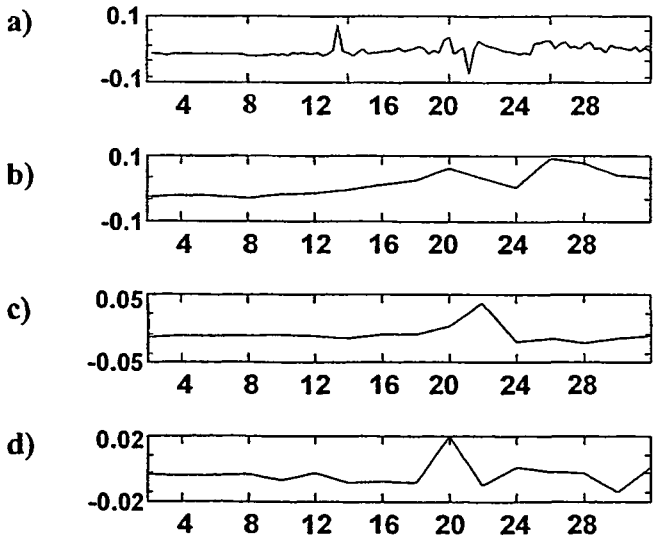
a)
0.1
-0.1
4 8 12 16 20 24 28
b)
0.1
-0.1
4 8 12 16 20 24 28
c)
0.05
-0.05
4 8 12 16 20 24 28
d)
0.02
-0.02
4 8 12 16 20 24 28
Time [days]

FIG. 12

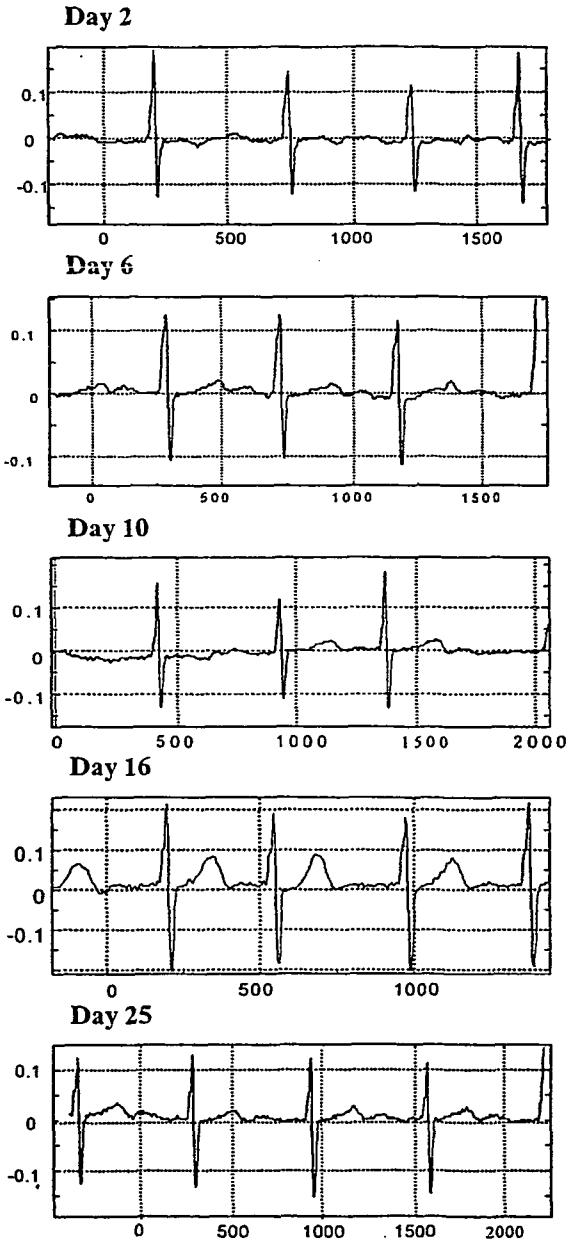
Day 2
0.1
0
-0.1
0
500
1000
1500
Day 6
0.1
0
-0.1
0
500
1000
1500
Day 10
0.1
0
-0.1
0
500
1000
1500
2000
Day 16
0.1
0
-0.1
0
500
1000
Day 25
0.1
0
-0.1
0
500
1000
1500
2000

FIG. 13

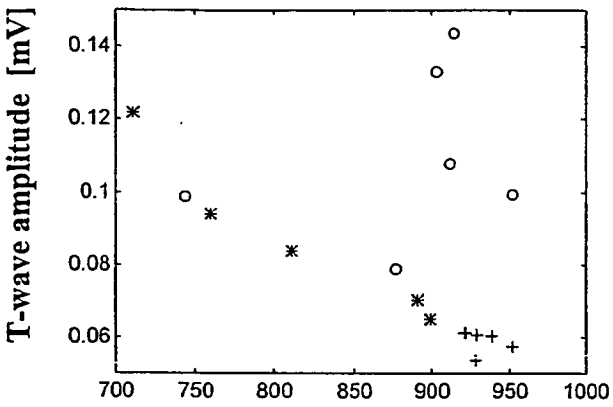
T-wave amplitude [mV]
0.14
0.12
0.1
0.08
0.06
700
750
800
850
900
950
1000
Duration of QT-interval [ms]

FIG. 14

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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- US 4679144 A **[0009]**
- US 5033475 A **[0009]**
- US 5501229 A **[0009]**
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- US 5967995 A **[0010]**

专利名称(译)	用于多尺度分析和表示心电图数据的系统和设备		
公开(公告)号	EP1284645B1	公开(公告)日	2008-05-14
申请号	EP2001939644	申请日	2001-05-29
[标]申请(专利权)人(译)	舒斯特曼VLADIMIR		
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IPC分类号	A61B5/0402 A61B5/04 A61B5/00 A61B5/0452		
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其他公开文献	EP1284645A2 EP1284645A4		
外部链接	Espacenet		

摘要(译)

系统包括医疗设备和方法，用于分析生理和健康数据并表示不同细节水平的最重要参数，这对于非专业人员和医疗专业人员来说是可理解的。低，中，高分辨率标度可以相互交换信息，以改进分析;可以根据相应的软件和硬件资源来定义比例。低分辨率标度I表示少量主要元素，例如心跳之间的间隔，心电图PQ，QRS和QT间隔的持续时间，P-，Q-，R-，S-和T-的幅度。波浪。该实时分析在需要最少计算资源的便携式设备中实现。可以使用中间或高分辨率级别调整主要元素集及其搜索条件。在中等分辨率标度II处，可以使用数学分解确定基本函数系列及其系数来确定每个所述元素的连续变化。可以使用专用处理器或计算机管理器来实现该比例。在高分辨率Scale III中，可以确定所有主要元素的组合序列变化，以提供有关信号动态的完整信息。可以使用功能强大的处理器，计算机网络或Internet来实现此扩展。该系统可用于个人或团体自我评估，紧急或常规ECG分析，或连续事件，压力测试或床边监测。