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Logier et al.(10) **Pub. No.: US 2017/0172443 A1**(43) **Pub. Date: Jun. 22, 2017**(54) **METHOD, DEVICE, SYSTEM AND
COMPUTER PROGRAMME FOR
FILTERING AN RR SERIES OBTAINED
FROM A CARDIAC SIGNAL WITH
AUTOMATIC CHECKING OF THE QUALITY
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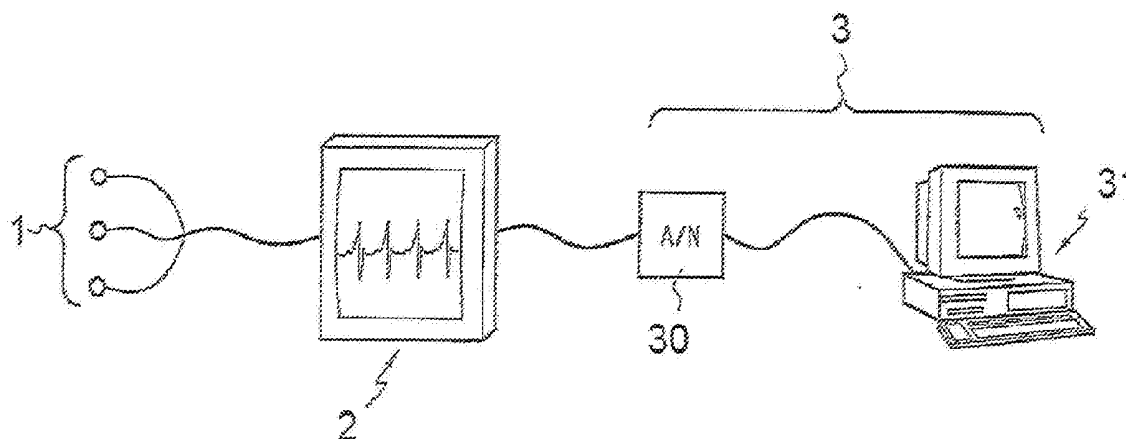
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(57)

ABSTRACT

The method is used for filtering an initial RR series of a plurality of (RRi) samples which are respectively a function of the time intervals (δt_i) that separate two successive heartbeats. In order to carry out this filtering, one must automatically detect in the initial RR series if one or more successive (RRi) samples are incorrect, and automatically correct in the RR series one or more of the (RRi) samples detected as being incorrect by replacing them with one or more reconstructed (RRc) samples so as to obtain an RR series. One must automatically control the quality of the RR series by counting, in a predefined sliding window, the number (NbPertub) of (RRc) samples of the RR series that were reconstructed, and/or, if applicable, the number (Nb-Pertub) of (RRc) samples of the RR series that were reconstructed and resampled.



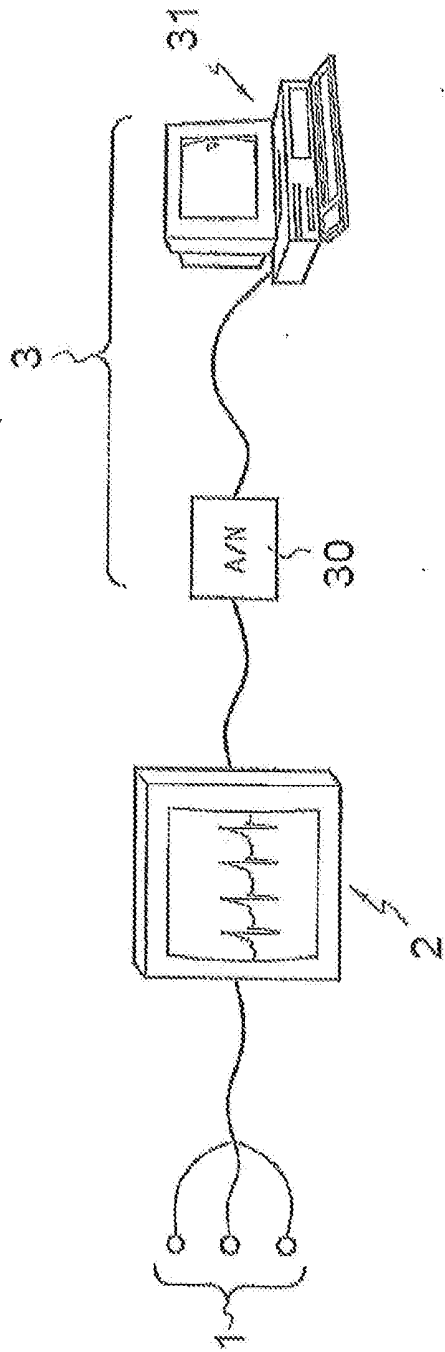


FIG. 1

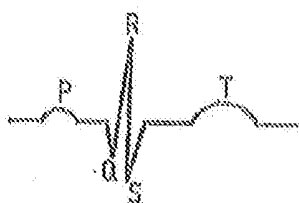


FIG. 2

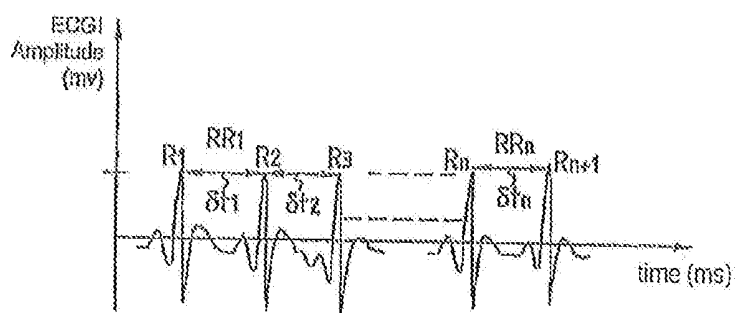


FIG. 3

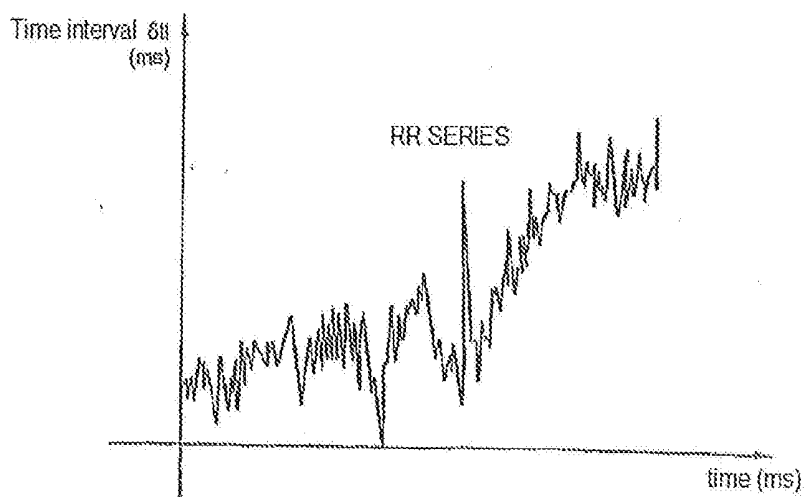


FIG. 4

**METHOD, DEVICE, SYSTEM AND
COMPUTER PROGRAMME FOR
FILTERING AN RR SERIES OBTAINED
FROM A CARDIAC SIGNAL WITH
AUTOMATIC CHECKING OF THE QUALITY
OF THE RR SERIES**

FIELD OF THE INVENTION

[0001] The present invention relates to the field of digital processing of a bioelectrical signal, which is characteristic of the cardiac rhythm of a living being, and which is designated in the present text by the term cardiac signal. This is for example, but not exclusively, an electrocardiographic (ECG) signal. In this technical field, the invention relates to the filtering of an RR series obtained by sampling a cardiac signal, with implementation of an automatic quality control of the RR series.

PRIOR ART

[0002] From a physiological perspective, the heart of a living being, isolated from outside influence, contracts automatically and very regularly as does a metronome, under the action of the sinus node which generates an independent nerve impulse and, thereby, causes a spontaneous cardiac muscle contraction. The heart is not, however, isolated; rather, it is connected to the autonomic nervous system (ANS) via parasympathetic and sympathetic systems. The autonomic nervous system influences the activity of the heart: the sympathetic system accelerates the heart rate, while the parasympathetic system slows it down. Thus, despite a certain degree of autonomy, the heart undergoes influences from the autonomic nervous system, which allows, in particular, the body of a living being to adapt the heart rate depending on its needs, however within reasonable limits. It is understood, therefore, that the analysis of the evolution of the heart rate over time, and in particular changes in the heart rate (changes in the heart beat), provides important information on the activity of the cardiac system, particularly on the activity of the autonomic nervous system. Now, knowledge of ANS activity can be of great help in the development of a diagnosis of many clinical situations. On this subject, reference may be made, for example, to the following publication: Lacroix D, Logier R., Kacet S., Hazard J-R, Dagano J. (1992): "Effects of consecutive administration of central and peripheral anticholinergic agents on respiratory sinus arrhythmia in normal subjects, J. of the Autonomic Nervous System", Vol 39, pages 211-218.

[0003] To study these fluctuations in heart rate, various filtering techniques and spectral analysis of a signal representing the evolution over time of the instant heart rate (or frequency) have already been developed since 1970, such signal which is obtained after sampling an analog bioelectrical signal characteristic of the heartbeat of a living being, and termed afterwards "analog cardiac signal."

[0004] To acquire this cardiac signal, different techniques of invasive or non-invasive acquisition are known. One known invasive technique is, for example, to use a blood pressure sensor connected to a catheter inserted into an artery. Among the known non-invasive methods are included, for example, the use of an infrared pulse sensor, or the acquisition of an electrocardiographic (ECG) signal using an electrocardiograph. This latter method of acquiring an ECG signal is in practice the most commonly used to

date, because, in addition to its noninvasive nature, it advantageously provides a more accurate signal than that which is obtained, for example, by means of an infrared pulse sensor.

[0005] The ECG signal is known as consisting of a succession of electrical depolarizations whose appearance is shown in FIG. 3 attached. The P wave, which corresponds to the depolarization of the atria, has a low amplitude and a dome shape. The PQ space reflects the time of atrioventricular conduction. The QRS complex reflects the ventricular contraction, and the T wave the ventricular repolarization. In practice, the peak R is considered as a marker of the ventricular systole, that is to say, of the heart beat.

[0006] In practice, the R wave usually being the finest and most extensive part of the QRS, it is generally used to locate the heart beat with very good accuracy, in practice of the order of one thousandth of a second. Thus, the time interval between two successive R waves accurately characterizes the time separating two successive heartbeats; this is the period of the ECG signal, and the inverse of this period gives the instantaneous heart rate.

[0007] To automatically construct the signal, called afterwards the RR series, representing the evolution in time of the instantaneous heart rate, the ECG signal, which is an analog signal (analog/digital conversion of the ECG signal), is sampled, and the sampled digital ECG signal is processed by automatically detecting R waves in this digital signal. An RR series is thus, in a conventional manner, comprised of a plurality of successive RR_i samples (or points), each RR_i sample being a function of the time interval between two successive R waves of the ECG signal.

[0008] However, it should be noted, on the one hand, that the other waves of depolarization (P, Q, S or T) of the ECG signal can also be used for characterizing the heart rate, even if the measurement accuracy is not as good as when using the R waves. On the other hand, depending on the acquisition technique chosen, the cardiac signal may have a different shape from that of the above mentioned ECG signal. The cardiac signal is not necessarily analog, but may be a digital signal. Accordingly, in the present text, the term RR series is not limited to the aforementioned specific definition based on the R waves of an ECG signal, but is defined in a more general way in the context of the present invention as a series of several digital samples called RR, obtained from a cardiac signal that is characteristic of the heart rate, each RR_i sample being a function of the time interval between two successive heartbeats. Each RR sample may be proportional, and in particular equal, to the time interval between two successive heartbeats, or inversely proportional to the time interval between two successive heartbeats.

[0009] In practice, disturbances in the cardiac signal, especially in an ECG signal, induce, in the RR series issued from this cardiac signal, abrupt changes of short duration, commonly called artifacts.

[0010] Disturbances, causing artifacts in the RR series, may be physiological and intrinsically linked to a temporary malfunction of the cardiac system; it may be, for example, an extrasystole. These disturbances may also be external and not related to the functioning of the cardiac system; it may be, for example, due to a patient's movement, briefly altering the measurement signal.

[0011] Artifacts in an RR series may result in a single incorrect sample or in a plurality of successive incorrect samples. In practice, an artifact in the RR series can be

likened to a Dirac pulse, and is reflected, in the frequency domain, by a rectangular continuous broadband spectrum. Therefore, assuming that a series RR could be transposed in the frequency domain (by Fourier transform or other), without first taking special precautions, the presence of artifacts in the RR series would result in the frequency domain by obtaining a very disturbed frequency spectrum of the RR series, of rectangular broadband shape, masking the spectrum of the real signal.

[0012] For this reason, to obtain accurate frequency information, it is essential to eliminate the artifacts before performing the frequency transposition.

[0013] It was thus proposed, in international patent application WO 02/069178, as well as in the article from Logier R, De Jonckheere J, Dassonneville A., "An efficient algorithm for R-R intervals series filtering". Conf Proc IEEE Eng Med Biol Soc. 2004; 6:3937-40, digital filtering algorithms, which generally allow filtering in real time a series RR obtained from a cardiac signal, by automatically detecting in the RR series the presence of one or more successive incorrect RR_i samples, and by automatically replacing in the RR series the incorrect RR_i samples that were detected by corrected RR_c samples. Detecting incorrect RR_i samples may be performed in various ways and the corrected (RR_c) samples may also be calculated in various ways, and for example, and for example, but not exclusively, by linear interpolation.

[0014] A problem of these filtering algorithms, designated subsequently algorithms or filtering method "with reconstruction of incorrect samples of an RR series", lies in the fact that the reconstruction of the RR series by replacing incorrect RR_i samples which were detected by corrected RR_c samples, can result in a final RR series partly rebuilt which is itself partially or completely distorted, especially when the cardiac signal that was taken is of poor quality. The lack of quality of this cardiac signal may be the result of many factors, such as, for example, and in a non-limiting, non-exhaustive manner, poor positioning of the electrodes or sensors of the heart signal, insufficient signal amplification in the signal processing chain, etc. . . .

[0015] But the reconstruction of a distorted RR series has not so far been detected by the filtering algorithms in a series RR. It follows that the information provided by these filtering algorithms can be completely wrong or insignificant without anyone noticing.

Purpose of the Invention

[0016] The present invention aims at providing a filtering solution of an RR series obtained from a cardiac signal, which implements an automatic reconstruction of incorrect samples of the RR series, but which can automatically control the quality of the RR series partly reconstructed.

SUMMARY OF THE INVENTION

[0017] The first purpose of the invention is thus a filtering method of an initial RR series consisting of a plurality of samples (RR_i) which are respectively a function of time intervals (δti) which separate two successive heartbeats, filtering method in which one automatically detects, in the original RR series, if one or more successive samples (RR_i) are incorrect, and one automatically corrects, in the RR series RR, the (RR_i) sample(s) detected as being incorrect by replacing them with one or more reconstructed samples

(RR_c), in order to obtain a partly reconstructed series RR, optionally, and in which new samples of the RR series are optionally collected so as to obtain a RR series, if necessary partly reconstructed and re-sampled. Characteristically, in accordance with the invention, the quality of the RR series is automatically controlled by counting in a predefined sliding window, the number ($NbPertub$) of (RR_c) samples of the RR series which were reconstructed and/or, optionally, the number ($NbPertub$) of (RR_{rc}) samples of the RR series which were reconstructed and re-sampled.

[0018] In this text, and particularly in the claims, the term "cardiac signal" means any physical signal characteristic of the instantaneous heart rate (or frequency) of a living being. For the implementation of the invention, various invasive or non-invasive techniques can be used to acquire the cardiac signal. One known invasive technique consists, for example, in using a blood pressure sensor connected to a catheter inserted into an artery. Among the known non-invasive methods (and which is preferable) are, for example, one which consists in using an infrared pulse sensor, using an ultrasonic sensor for detection of the cardiac cycles, the type of sensor implemented in a cardiotocograph, or the acquisition of an electrocardiographic (ECG) signal. The acquisition of an electrocardiographic (ECG) signal is in practice the most commonly used method, because besides its non-invasive nature, it provides a more accurate cardiac signal than that obtained, for example, by means of an infrared pulse sensor.

[0019] In this text, and particularly in the claims, the term "RR series" generally means a series of various successive samples RR, obtained from a cardiac signal characteristic of the cardiac rhythm of a living being, each RR_i sample being generally based on a time interval (δti) between two successive heartbeats. Generally, each sample (RR_i) is proportional, in particular equal, to the time interval (δti) between two successive heartbeats. Each (RR_i) sample may also be proportional, and more particularly equal to the inverse ($1/\delta ti$) of the time interval between two successive heartbeats.

[0020] In the preferred exemplary embodiment described below with reference to the accompanying figures, the RR series is more particularly constructed from the R waves of an ECG signal. This is not, however, limiting the invention. In the case of an ECG type cardiac signal, one can build the series called "RR" using the other depolarization waves (P, Q, S or T) of the ECG signal to construct the RR series, the accuracy not being however as good as when using the R waves of the ECG signal. Also, when the cardiac signal is not an ECG signal, the samples of the RR series are not calculated by determining the time interval (δti) separating two successive R waves of the ECG signal, but are, more generally, determined by detecting in the cardiac signal the time interval between two successive heartbeats.

[0021] More particularly, but optionally according to the invention, the method of the invention may include additional and optional technical characteristics below, considered individually or in combination:

[0022] It automatically calculates a quality index (NivQual) which is significant for the quality of the RR series, and which depends on the number ($NbPertub$) of samples (RR_c) of the RR series that were reconstructed and/or, optionally, the number ($NbPertub$) of samples (RR_{rc}) of the RR series that were reconstructed and re-sampled.

[0023] The quality index (NivQual) also depends on the instantaneous heart rate FCi, with $FCi = 60000/RRi$, RRi being the instantaneous value in a millisecond of a sample (RRi) of the RR series, optionally partly reconstructed.

[0024] The quality index (NivQual) also depends on the mathematical norm value, within said sliding window, of the RR series, optionally partly reconstructed and resampled, said mathematical norm value being given by the following formula:

$$NORME = \sqrt{\sum_{i=1}^N \left(RR_i - \frac{1}{N} \sum_{i=1}^N (RR_i) \right)^2}$$

where N is the number of RRi samples in said window.

[0025] An action is automatically triggered when the number (NbPertub) of samples

[0026] (RRc) of the RR series that were reconstructed and/or, optionally, the number (NbPertub) of samples (RRrc) of the RR series that were reconstructed and resampled, is greater than a preset value (THRESHOLD 1).

[0027] An action is automatically triggered when the number (NbPertub) of samples (RRc) of the RR series that were reconstructed and/or, optionally, the number (NbPertub) of samples (RRrc) of the RR series that were reconstructed and resampled, is greater than at least a quarter of the number (N) of samples (RRi) in the window.

[0028] An action is automatically triggered when the mathematical norm value (NORME) calculated is outside a predefined range (NormMin; NormMax).

[0029] An action is automatically triggered when the instantaneous heart rate (FCi) calculated is outside of a predefined range (FCMin; FCMax).

[0030] The action that is triggered includes triggering a visual and/or audible alarm.

[0031] The action that is triggered includes resetting the acquisition and construction of samples (RRi) of the initial RR series.

[0032] The method that includes the acquisition and construction in real time of the successive samples (RRi) of the initial RR series from a cardiac signal, the detection and correction of incorrect samples (RRi) as well as counting of the reconstructed samples are performed in real time while said acquisition and construction of successive samples (RRi) of the RR series are taking place.

[0033] The invention also relates to a device for filtering a RR series consisting of a plurality of samples (RRi) which are respectively based on the time intervals (δti) separating two successive heartbeats, said device being designed to automatically filter the RR series and to control the quality of this RR series by implementing the aforementioned method.

[0034] Another purpose of the invention is a data acquisition and processing system for a cardiac signal, said system comprising electronic means for acquiring a cardiac signal, and electronic processing means designed for constructing an RR series, from the cardiac signal acquired by the electronic acquisition means, said RR series consisting of a plurality of samples (RR_i) which are respectively a function of the time intervals (δti) separating two successive heartbeats of the cardiac signal. Typically according to the invention, said electronic processing means are designed to

automatically filter the RR series and to control the quality of this RR series by implementing the aforementioned method.

[0035] The invention also provides a computer program comprising means for coding a computer program adapted to be executed by electronic processing means, and, when executed by electronic processing means, for implementing the filtering method of the aforementioned RR series.

BRIEF DESCRIPTION OF FIGURES

[0036] Other features and advantages of the invention will appear more clearly upon reading the detailed description below of a preferred embodiment of the method of the invention, said detailed description being given by way of non-limiting and non-exhaustive example, with reference to the accompanying drawings in which:

[0037] FIG. 1 schematically represents the main elements of an exemplary acquisition and processing system of an ECG signal implementing the method of the invention,

[0038] FIG. 2 represents the set of waves (PQRST) characteristic of a cardiac beat in an ECG signal,

[0039] FIG. 3 shows an example of digital ECG signal obtained after sampling an analog ECG signal,

[0040] FIG. 4 shows an example of an RR series (still designated as RR signal) constructed from the signal of FIG. 3.

DETAILED DESCRIPTION

System for Acquiring and Processing the Cardiac Signal

[0041] FIG. 1 shows an example of an acquisition and processing system of the cardiac signal of a living being (human or animal) that is used for the implementation of the method according to the invention.

This system comprises:

[0042] conventional electronic means for acquiring an ECG signal, comprising several measuring electrodes 1 connected at their input to an electrocardiographic (ECG) monitor 2,

[0043] electronic means 3 for processing the ECG signal outputted by the ECG monitor 2.

[0044] The processing means 3 of the ECG signal comprises an analog/digital converter 30, and an electronic processing unit 31. The input of converter 30 is connected to the output of the ECG monitor 2, and the output of the converter 30 is connected to an input port of the electronic processing unit 31. In one particular non-limiting embodiment of the invention, the processing unit 31 is constituted by a microcomputer, the converter 30 being connected to a serial port RS232 of this microcomputer. The invention is not limited to the implementation of a microcomputer as the electronic processing unit 31 can be implemented differently, for example as an FPGA type programmable electronic circuit, or as an integrated ASIC type circuit.

[0045] In operation, the electrodes 1 are applied to the body of the living being, and the ECG monitor 2 outputs in the usual way an analog electrical signal, called ECG signal, that has the shape of the signal shown in FIG. 2 for each heart beat.

[0046] Referring to FIG. 2, for each heart beat, this electrocardiographic (ECG) signal consists of a set of electric waves:

[0047] the P wave, which corresponds to the depolarization of the atria, and which has a small amplitude and a dome shape;

[0048] the PQ space which reflects the time of atrio-ventricular conduction;

[0049] the R wave, regarded in practice as a marker of ventricular systole, or the heart beat, the QRS complex reflecting ventricular contraction, and

[0050] the T wave which reflects ventricular repolarization.

[0051] This analog ECG signal is digitized by the converter 4 with a predetermined sampling frequency (f_c), equal for example to 256 Hz.

[0052] The sampled signal output from the converter 30 (signal shown in FIG. 3) is processed by the processing unit 31 by means of specific processing software (filtering software) which is described in detail below. This filtering software is stored in memory of the processing unit 31 and allows, when executed, automatically constructing, from the digital signal delivered by the analog/digital converter 30, an RR series with, optionally, automatic reconstruction of incorrect samples RR_i , and automatically calculating a NivQual quality index that can control the quality of the RR series, optionally partly reconstructed.

[0053] A preferred variant of this filtering software will now be detailed.

Example of Filtering Software Algorithm

[0054] In a particular variant embodiment of the invention, the main successive steps of the filtering algorithm are the following:

[0055] 1. Acquisition and construction of RR_i samples from the signal output from the analog/digital converter 30.

[0056] 2. Filtering the RR series with optional automatic detection of incorrect samples RR_i , and substituting with reconstructed samples identified in the RR_c samples series.

[0057] 3. Re-sampling of the RR series to a predefined frequency f to obtain resampled RR_i samples.

[0058] 4. Selection of RR_i samples included in a time window of n seconds ($n > 1/f$).

[0059] 5. Calculating a NivQual quality index

[0060] 6. Offsetting, with a time step equal to p seconds (preferably $p \leq n$), the time window of n seconds, and reiterating the calculation from step 2. This offset corresponds to the sliding of the time window for selecting the samples.

[0061] In practice, the system can be programmed to be used in real time or delayed time.

[0062] When the system is used in delayed time, step 1 is performed first in real time so as to build all RR_i samples over all the period of analysis desired; all of these successive RR_i samples are stored in memory, for example in a memory acquisition file of the processing unit 31. Secondly, the steps 2-6 are performed in a loop, offline, on the RR_i samples stored in the acquisition file.

[0063] When the system operates in real time, step 1 of construction of the RR_i samples on the one hand, and the other processing steps 2-6 on the other hand, are performed by two separate software modules operating in parallel, the first construction module (step 1) supplying the second processing and calculation module (steps 2-6) for example through a buffer file or register or equivalent.

[0064] Steps 1-5 will now be detailed.

Step 1: Acquisition and Construction of RR_i Samples

[0065] The acquisition and construction of the RR_i samples are performed by a first software sub-module which

is input with the successive digital data constituting the digitized ECG signal (signal of FIG. 3) output by the analog digital converter 30. Each data (or point) of the ECG signal is determined by the instantaneous amplitude ECG_i of the ECG signal, and by sampling time t_i ($t_i = n_i/f_c$, with n_i being the sample number and f_c representing the sampling frequency of the converter 30).

[0066] The first acquisition sub-module of RR_i samples is designed to automatically detect each successive R_i peak in the digital signal delivered by the converter 30, and to automatically construct an RR series (FIG. 4) consisting of a succession of RR_i samples. Each RR_i sample is defined by the pair of coordinates: t_i [a sampling moment (or number)]; a time interval δt_i (expressed as a multiple of the sampling frequency f_c) separating a peak R_i from the next peak R_{i+1} (in another embodiment it could be the previous peak R_{i-1}).

[0067] In the usual manner, the R wave usually being the finest and most extensive part of the QRS, it is preferably used to detect heart beat with very good accuracy, the time interval δt_i corresponding in practice to the time between two successive heartbeats. However, in another variant, one might consider using other waves (such as Q wave or S wave) of a heart beat of the ECG signal to detect and construct the RR series. In another variant, one could also consider using other cardiac signals such as the plethysmograph waveform or the invasive blood pressure.

Step 2: Filtering the RR Series with Optional Automatic Detection of Incorrect RR_i Samples and Replacement by RR_c Reconstructed Samples

[0068] This filtering step consists generally in automatically detecting in the RR series the presence of one or more incorrect successive RR_i samples, and automatically replacing in the RR series the incorrect RR_i samples that were detected by reconstructed RR_c samples. The number of reconstructed RR_c samples is, most of the time, different from the number of incorrect samples that were detected.

[0069] This filtering step with automatic reconstruction of incorrect RR_i samples is known per se, and examples of implementation of this filtering step are described for example in international patent application WO 02/069178, as well as in the article Logier R, De Jonckheere J, Dassonneville A., <<An efficient algorithm for R-R intervals series filtering>>. Conf Proc IEEE Eng Med Biol Soc. 2004; 6:3937-40.

[0070] It should however be noted that in the context of the invention, the detection of incorrect RR_i samples is not limited to the detection methods described in the two aforementioned publications, and reconstructed RR_c samples can also be calculated in various ways, such as, for example but not exclusively, by linear interpolation, as described in the two abovementioned publications.

[0071] Each reconstructed RR_c sample of the RR series is identified, for example by an associated flag type identification variable. Thus, after this step, the RR series consists of RR_i samples some of which are, optionally, identified by their identification variable as reconstructed RR_c samples.

Step 3: Resampling of the RR Series to a Predefined Frequency f to Obtain Resampled RR_i Samples

[0072] The filtered RR series (FIG. 4) supplied by the aforementioned first sub-module is automatically resampled by a second software sub-module at a predefined frequency f , which is preferably lower than the sampling frequency f_c (for example, for a sampling frequency f_c equal to 250 Hz, the resampling frequency f will be set to 8 Hz). The purpose of this resampling is to output an RR series whose RR_i samples are equidistant from a temporal point of view, that

is to say, in other words an RR series in which the sampling instants are regular. This resampling is carried out in known manner by interpolation, for example by linear interpolation.

[0073] During this resampling, each reconstructed RRc sample is replaced, as appropriate, by one or more reconstructed and resampled RRrc samples.

[0074] Each reconstructed and resampled RRrc sample of the RR series is identified, for example by an associated flag type identification variable. Thus, after this step, the RR series consists of RRi samples some of which are, optionally, identified by their identification variable as reconstructed and resampled RRrc samples.

Step 4: Selection of RRi Samples (of the RR Series, Optionally Partly Reconstructed and Resampled) Included in a Main Time Window of n Seconds ($n > 1/f$)

[0075] This step consists in isolating a number N of successive RRi samples ($N = n \cdot f$). As an indication, for example, a main window of 64 seconds ($n = 64$) is chosen, which corresponds to 512 successive RRi samples ($N = 512$) at a resampling frequency f of 8 Hz.

[0076] The following steps are applied to the samples included in this main window.

Step 5: Calculation of a NivQual Quality Index

[0077] This step is performed using a software sub-module that automatically calculate a NivQual quality index significant of the quality of the RR series.

[0078] In the particular embodiment described in detail below, this NivQual quality index has four quality levels from 0 to 3; the higher the index, the more reliable the RR series from step 1 is.

[0079] More particularly, the NivQual quality index is based on three variables (FC_i ; NORME; NbPertub) which are calculated in Step 5:

[0080] 1/ the value of the instantaneous heart rate (FC_i) calculated on each RRi sample of the RR series from Step 2, that is to say, the RR series after filtering (optionally partly reconstructed) and before resampling.

[0081] 2/ the mathematical norm value (NORME) of the RR samples of the RR series (optionally partly reconstructed and resampled) from selection Step 4 in the time window of n seconds.

[0082] 3/ the number (NbPertub) of reconstructed and resampled RRrc samples contained in the time window of n seconds (or the number of reconstructed RRc samples corresponding to the reconstructed and resampled RRrc samples contained in the time window of n seconds).

[0083] The heart rate is defined by $FC_i = 60000/RR_i$, where RR_i is the instantaneous value of the RR_i sample in millisecond.

[0084] Calculating the mathematical norm value of the RR series resampled at the frequency f in the window of n seconds consists initially in calculating the average value M of RR_i in the window.

$$M = \frac{1}{N} \sum_{i=1}^N (RR_i)$$

where RR_i represents the value of each RR interval and N the number of samples in the window.

[0085] This average value is then subtracted at each RR_i interval of the window.

$$RR_i = (RR_i - M),$$

[0086] The RR_i values obtained are used for the calculation of the norm value (NORMS), or:

$$NORME = \sqrt{\sum_{i=1}^N \left(RR_i - \frac{1}{N} \sum_{i=1}^N (RR_i) \right)^2}$$

[0087] When taking into account the number (NbPertub) of the reconstructed and resampled RRrc samples contained in the time window of n seconds, it is considered that if the filter (Step 2) replaced too large a share of incorrect RRi samples by reconstructed RRc samples in the window of n seconds, the RR signal is, in fact, impossible to interpret.

[0088] Thus, in a first variant, the number (NbPertub) of reconstructed and resampled RRrc samples contained in the time window of n seconds is automatically counted, and this number (NbPertub) is used in Step 5 to calculate the NivQual quality index.

[0089] In a second variant, the number (NbPertub) of reconstructed RRc samples corresponding to reconstructed and resampled RRrc samples contained in the time window of n seconds is automatically counted, and this number (NbPertub) is used in Step 5 to calculate the NivQual quality index.

[0090] The aforementioned second variant may be implemented with or without resampling the RR series. In this case, the calculation of NbPertub number can be performed by automatically counting, in the RR series obtained from the filtering Step 2, the number of RRc samples of the RR series that were reconstructed, in a sliding window comprising a predefined number (N) of samples and equivalent to a time window. In this case, the aforementioned Step 6 consists in offsetting the calculation window of a predefined number p of samples (preferably $p \leq N$), and repeating the calculation from Step 2. This offset corresponds to the sliding of the sample selection window.

[0091] The first and second variants above may also be combined.

[0092] An example of algorithm for calculating the NivQual quality index from the three aforementioned variables (FC_i ; NORME; NbPertub) is given below:

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If
  ((NORME < NormMin)
  or
  (NORME > NormMax)
  or
  (FCi > FCMax)
  or
  (FCi < FCMin)
then Nivqual = 0
IF NOT
  If NbPerturb ≥ THRESHOLD1 then NivQual=0
  If (NbPerturb < THRESHOLD1) and (NbPerturb ≥ THRESHOLD2)
  then NivQual=1
  If (NbPerturb < THRESHOLD2) and (NbPerturb ≥ THRESHOLD3)
  then NivQual=2
  If NbPerturb < THRESHOLD3 then NivQual=3

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[0093] The values of the FCMax, FCmin, NormMax, NormMin parameters are predefined constants, which depend, for example, on the age of the human being or depend, for example, on the animal species in the context of a veterinary application. The values of the FCMax, FCmin thresholds are those commonly used by all heart monitoring devices. The values of NormMax, NormMin thresholds of

the norm value are, for example, experimentally determined on 200 individuals in each category.

[0094] By way of non-limiting example:

[0095] for a newborn: FCMax=250; FCMin=80; NormMax=3; NormMin=0

[0096] for an adult: FCMax=180; FCMin=30; NormMax=4; NormMin=0.07

[0097] The values of the THRESHOLD1, THRESHOLD2, THRESHOLD3 parameters are predefined constants, which depend on the number N (N=n.f) of RR_i samples in the window of n seconds.

[0098] For example, the value of THRESHOLD1 can be set to one quarter of the number N (N=n.f) of RR_i samples in the n seconds window, or THRESHOLD1=N/4. The value of THRESHOLD2 may be set to an eighth of the number N (N=n.f) of RR_i samples in the n seconds window, or THRESHOLD2=N/8. The value of THRESHOLD3 may be set to one sixteenth of the number N (N=n.f) of RR_i samples in the n seconds window, or THRESHOLD3=N/16.

[0099] The NivQual quality index calculated at each Step 5 may, for example, be displayed, especially in real time, so as to inform a practitioner of the quality level of the measured RR signal.

[0100] In the case of a NivQual quality index equal to 0, the RR series from Step 1 is considered as being of very poor quality and in fact unusable. This lack of quality of the RR series may result from many factors, such as, for example, and in a non-limiting and non-exhaustive manner, improper positioning of the electrodes 1 or the sensors for measuring the heart signal, insufficient signal amplification in the signal processing chain, etc.

[0101] When calculating a NivQual quality index equal to 0, processing unit 31 can be programmed to automatically trigger several actions, including and not limited to, triggering of a visual and/or audible alarm, and/or resetting acquisition Step 1 of RR_i samples, including, in particular, a manual or automatic gain change of the source signal (ECG).

[0102] In the context of the invention, for the implementation of Step 5, the NivQual quality index calculation algorithm can be simplified by taking into account only the number NbPertub mentioned above, and by not taking into account the two other FC_i and NORME parameters, or by taking into account the number NbPertub mentioned above and only one of the two other parameters, FC_i or NORME.

[0103] When the NivQual quality index does not take into account the NORME parameter, re-sampling Step 3 is not necessary and may be omitted.

1. A method for diagnosing a cardiac condition of a subject based on filtering an initial RR series comprised of a plurality of samples (RR_i) of a cardiac signal which are respectively a function of time intervals (δt_i) which separate two successive heartbeats, filtering process in which one automatically detects in the initial RR series if one or more successive (RR_i) samples are incorrect, and automatically corrects, in the RR series, the (RR_i) sample(s) detected as being incorrect by replacing them by one or more reconstructed (RRc) samples so as to obtain an RR series optionally partly reconstructed, and during which one optionally resamples the RR series in order to obtain an RR series, optionally partly reconstructed and resampled, comprising automatically controlling the quality of the RR series by counting, in a predefined sliding window, the number (NbPertub) of (RRc) samples of the RR series that were recon-

structed the number (NbPertub) of (RRc) samples of the RR series that were reconstructed and resampled, or a combination thereof; and

diagnosing the cardiac condition of the subject based on the RR series.

2. The method of claim 1, wherein one automatically calculates a (NivQual) quality index which is indicative of the quality of the RR series, and which depends on the number (NbPertub) of (RRc) samples of the RR series that were rebuilt and/or, if applicable, the number (NbPertub) of (RRc) samples of the RR series that were reconstructed and resampled.

3. The method of claim 2, wherein the (NivQual) quality index also depends on the instantaneous heart rate FC_i, with FC_i=60000/RR_i, RR_i being the instantaneous value in millisecond of an (RR_i) sample of the RR series, optionally partly reconstructed.

4. The method according to claim 2, wherein the (NivQual) quality index also depends on the mathematical norm value, within said sliding window, of the RR series, optionally partly reconstructed and resampled, said mathematical norm value being given by the following formula:

$$NORME = \sqrt{\sum_{i=1}^N \left(RR_i - \frac{1}{N} \sum_{i=1}^N (RR_i) \right)^2}$$

where N is the number of RR_i samples in said window.

5. The method according to claim 1, wherein one automatically triggers an action when the number (NbPertub) of (RRc) samples of the RR series that have been reconstructed the number (NbPertub) of the (RRc) samples of the RR series that were reconstructed and resampled, or the combination thereof, is greater than a preset value (THRESHOLD 1).

6. The method according to claim 1, wherein one automatically triggers an action when the number (NbPertub) of the (RRc) samples of the RR series that were reconstructed, the number (NbPertub) of the (RRc) samples of the RR series that were reconstructed and resampled, or the combination thereof, is greater than at least a quarter of the number (N) of the (RR_i) samples in the window.

7. The method according to claim 5, wherein the action that is triggered comprises the triggering of a visual alarm, an audible alarm, or a combination thereof.

8. The method according to claim 5, wherein the action that is triggered comprises resetting the acquisition and construction of the (RR_i) samples of the initial RR series.

9. The method according to claim 1, further comprising the acquisition and construction in real time of successive (RR_i) samples of the initial RR series from a cardiac signal, and wherein the detection and correction of incorrect (RR_i) samples as well as the counting of reconstructed samples are performed in real time while said acquisition and construction of successive (RR_i) samples of the RR series are taking place.

10. A filter device (3) of an RR series comprised of a plurality of (RR_i) samples which are respectively a function of time intervals (δt_i) separating two successive heartbeats, said device (3) being arranged so as to automatically filter the RR series and control the quality of this RR series by implementing the method described in claim 1.

11. An acquisition and processing system for a cardiac signal, said system comprising electronic acquisition means (1,2) of a cardiac signal, and electronic processing means (3) arranged so as to construct an initial RR series from the cardiac signal acquired by the electronic acquisition means (1,2), said RR series comprised of a plurality of (RRi) samples which are respectively a function of time intervals (δt_i) which separate two successive heartbeats of the cardiac signal, characterized in that said electronic processing means (3) are arranged so as to automatically filter the RR series and control the quality of this RR series by implementing the method referred to in claim 1.

12. A computer program comprising a computer program adapted to be executed by electronic processing means (3), and allowing, when executed by electronic processing means (3), to implement the filtering method of an RR series referred to in claim 1.

13. The method of claim 1, wherein both the number (NbPertub) of (RRc) samples of the RR series that were reconstructed and the number (NbPertub) of (RRrc) samples of the RR series that were reconstructed and resampled are calculated.

* * * * *

专利名称(译)	用于过滤从心脏信号获得的RR系列的方法，设备，系统和计算机程序，其自动检查RR系列的质量		
公开(公告)号	US20170172443A1	公开(公告)日	2017-06-22
申请号	US15/118409	申请日	2015-02-20
[标]申请(专利权)人(译)	里尔大学地区医疗中心 MDOLORIS医疗制度		
申请(专利权)人(译)	中心医院区域区大学里尔 MDOLORIS医疗系统		
当前申请(专利权)人(译)	中心医院区域区大学里尔 MDOLORIS医疗系统		
[标]发明人	LOGIER REGIS DE JONCKHEERE JULIEN JEANNE MATHIEU MARGEZ THOMAS		
发明人	LOGIER, REGIS DE JONCKHEERE, JULIEN JEANNE, MATHIEU MARGEZ, THOMAS		
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CPC分类号	A61B5/0456 A61B5/02455 A61B5/04018 A61B5/746 A61B5/0468 A61B5/044 A61B5/7405 A61B5/04028 A61B5/7221		
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摘要(译)

该方法用于过滤多个 (RRi) 样本的初始RR系列，其分别是分离两个连续心跳的时间间隔 (δt_i) 的函数。为了进行这种过滤，必须在初始RR系列中自动检测一个或多个连续 (RRi) 样本是否不正确，并在RR系列中自动校正被检测为不正确的一个或多个 (RRi) 样本。用一个或多个重建 (RRc) 样本替换它们以便获得RR系列。必须通过在预定义的滑动窗口中计算重建的RR系列的 (RRc) 样本的数量 (NbPertub) 和/或 (如果适用的话) 数量 (NbPertub) 来自动控制RR系列的质量。(RRc) 重建和重新采样的RR系列样本。

