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(54) **Device and computer-readable storage medium for detecting and classifying of cardiac events**

Vorrichtung und computerlesbares Speichermedium zur Detektion und Klassifizierung von kardialen Ereignissen

Dispositif et support de stockage lisible sur ordinateur pour détecter et classer des événements cardiaques

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Description

[0001] The present invention generally relates to implantable cardiac devices, including monitoring devices, pacemakers, defibrillators and cardioverters, which monitor, detect and classify cardiac events, for example atrial tachyarrhythmias. More particularly, the present invention relates to a device for detecting Atrial Fibrillation or Atrial Flutter by evaluating ventricular signals. Further, there is also disclosed a method for monitoring atrial events for use in implantable devices without atrial electrodes.

[0002] There are previously proposed methods for detecting atrial tachyarrhythmias and a determination of their being stable or unstable. Example devices and methods are disclosed in US 4, 880,005 and WO 02/056961 A2 disclosing the features of the first part of claims 1 and 11. However, an otherwise simple task is complicated by the fact that a multi-chamber pacemaker or ICD may not "see" all of the atrial complexes due to some of these falling in cross-chamber blanking periods, such as post-ventricular-pace blanking and far-field blanking periods.

[0003] It is known from the prior art to use a so called "X-out-of-Y" criterion to detect an ongoing atrial tachyarrhythmia. The US patent US 6,671,548 B1 for example describes use of such a "X-out-of Y" criterion. This criterion declares detection of an atrial tachyarrhythmia when X number of intervals among most recent Y number of atrial intervals are found to be shorter than an interval limit corresponding to the tachyarrhythmia rate limit. The numbers X, Y and the tachyarrhythmia rate limit may be user defined, e.g., pre-defined or may be programmable. As is clear, the "X-out-of-Y" criterion accommodates for undersensing of some of the atrial events.

[0004] It is an objective of the invention to provide a device, for example an implantable cardiac device, such as a monitoring device, especially a monitoring device without atrial electrodes, but also such as a pacemaker, a defibrillator or a cardioverter, for evaluating cardiac events, such as ventricular signals, for detecting atrial arrhythmia like Atrial Fibrillation or Atrial Flutter. The device comprises control and storage means and is arranged for executing a method for classifying atrial tachyarrhythmia.

[0005] The present invention utilises a method for detecting cardiac events, such as for example Atrial Fibrillation (AF) or termination of the AF. The method is based on the analysis of the instability observed in the heart rate, known to be caused by irregular conduction from the atrium during an episode of AF. Change in the heart interval is monitored on a beat-to-beat basis in an attempt to recognize the instability that indicates presence of an Atrial Fibrillation or Atrial Flutter. According to a preferred embodiment of the invention, the heart intervals are ventricular intervals. The number of false indications is reduced by incorporating features for recognizing Premature Ventricular Contractions and beat detections associated with noise. All clinically significant episodes can be detected. The number of false detections is kept at minimum and below a limit that is tolerated by the attending physician. The design is suitable for incorporation in an implantable device. This is a method, suitable for an implantable device, with high sensitivity and positive predictive values (very few false AF detections).

[0006] According to this method discrete packets of consecutive heart intervals are analyzed. The size n of the packet is predetermined. The packet can comprise for example 8, 16, 24, 32 or another number of intervals.

[0007] For at least a part of the consecutive intervals of the packet, differences between consecutive intervals in the packet are evaluated. However, preferably for each packet containing n intervals, n-1 such evaluations are made. The evaluation comprises comparison of the differences with a pre-determined stability limit. In a preferred embodiment the stability limit is calculated as a settable percentage of the average value of the intervals of the interval packet. The value can be programmed for example to 6.25%, 12.5% or 18.75%. In a preferred embodiment both, differences and stability limit are weighted. As weights any values may be used, preferably values of 1 or 2 may be used.

[0008] The percentage value for the stability limit for different cardiac events can be equal, or it can be chosen independently for each event. For example, the percentage value for the stability limit for AF detection may be equal to that of detection of termination of the AF, or it may be chosen independently for both, AF detection and termination detection.

[0009] According to the method an instability counter is calculated depending from the result of the comparison of the differences with the pre-determined stability limit. According to the invention, the instability counter is incremented for each evaluation that indicates instability as per the following test:

- the absolute value of the difference between a current interval of the packet and the preceding interval of the packet is greater than the stability limit, and
- the absolute value of the difference between twice the current interval of the packet and the preceding interval of the packet is greater than twice the stability limit, and
- the absolute value of the difference between the current interval of the packet and twice the preceding interval of the packet is greater than twice the stability limit.

[0010] Written in pseudo-code, the criterion reads:

Absolute [Current Interval - Preceding Interval] > Stability Limit; AND
Absolute [2 * Current Interval - Preceding Interval] > 2 * Stability Limit; AND
Absolute [Current Interval - 2 * Preceding Interval] > 2 * Stability Limit.

[0011] According to the invention a pre-determined event compare limit is used to confirm whether or not a packet analysis indicates presence of the cardiac event to be detected. To determine whether the cardiac event in the interval packet is indicated, the value of the instability counter is compared with the event compare count limit. In a preferred embodiment, a presence of AF is indicated if the instability counter is equal to or greater than the said AF compare count limit. In another preferred embodiment, an absence of AF is indicated if the instability counter is equal to or less than the said termination compare count limit. If the packet contains n intervals, the event compare count limit can be programmed in the range 1 to n-1, i.e. it depends from the chosen packet size.

[0012] A predetermined event packet hysteresis may also be used. The cardiac event is declared, if presence of the cardiac event is indicated in a pre-determined number of consecutive interval packets. For example, Atrial Fibrillation is declared, if presence of Atrial Fibrillation is indicated for a pre-determined number of consecutively analyzed interval packets. Analogously, termination of Atrial Fibrillation is declared, if absence of Atrial Fibrillation is indicated for a pre-determined number of consecutively analyzed interval packets. The event packet hysteresis can be programmed to 1, 2, 3 or 4, and depends preferably from the chosen packet size.

[0013] A further object of the invention is providing noise options and options for Premature Ventricular Contraction (PVC). It is proposed to execute for a heart beat which is associated with noise or for a heart beat which is recognized as a Premature Ventricular Contraction at least one of the following steps:

- the current heart interval and the following heart interval are excluded from analysis; and
- a new interval packet is created starting from the heart beat that follows the next heart beat.

[0014] In a preferred embodiment for each case, noise and PVC, there are four options proposed:

Noise options:

[0015]

1. For a heart beat associated with noise, the current and the following heart intervals are excluded from the analysis.

2. For a heart beat associated with noise, the instability counter is decremented by one and the current and the following heart intervals are excluded from the analysis. If the instability counter becomes zero, a new packet is created starting from the heart beat that follows the next heart beat. This Option can be used only when attempting to detect AF.

3. For a heart beat associated with noise, the instability counter is incremented by one and the current and the following heart intervals are excluded from the analysis. If the instability counter becomes equal to the termination compare count limit, it is cleared and a new packet is created starting from the heart beat that follows the next heart beat. This Option can be used only when attempting to detect termination of AF.

4. For a heart beat associated with noise, the instability counter is cleared and a new packet is created starting from the heart beat that follows the next heart beat.

PVC options:

[0016]

1. For a heart beat recognized as a Premature Ventricular Contraction (PVC), the current and the following heart intervals are excluded from the analysis.

2. For a heart beat recognized as a PVC, the instability counter is decremented by one and the current and the following heart intervals are excluded from the analysis. If the instability counter becomes zero, a new packet is created starting from the heart beat that follows the next heart beat. This Option can be used only when attempting to detect AF.

3. For a heart beat recognized as a PVC, the instability counter is incremented by one and the current and the following heart intervals are excluded from the analysis. If the instability counter becomes equal to the termination compare count limit, it is cleared and a new packet is created starting from the heart beat that follows the next heart beat. This Option can be used only when attempting to detect termination of AF.

4. For a heart beat recognized as a PVC, the instability counter is cleared and the current and a new packet is created starting from the heart beat that follows the next heart beat.

[0017] In summary, the method is based on evaluation of the variability of ventricular intervals during occurrence of atrial arrhythmia. According to a first step of the inventive method, a packet of a number of consecutive intervals is evaluated, whether the length of an interval is stable compared with the length of the preceding interval, or whether the length of the subsequent interval has changed. After detection of an instability, the instability counter is incremented.

[0018] The result of the stability test for a packet of intervals is represented by the value of the instability counter. Depending upon whether or not an Atrial Fibril-

lation (AF) has been declared, which is indicated by an AF status flag, different "X-out-of-Y" criterion are applied. The AF status flag is set or cleared when declaring an AF or when declaring termination of an AF respectively. After this, the instability counter is reset, and the next packet of intervals is evaluated.

[0019] The implantable device is realized as a pure monitoring device, which does not stimulate the heart. In contrast to the prior art, such an implantable device does not comprise cardiac electrodes. Instead, in a preferred embodiment the inventive implantable device detects respective electrical potential with the help of electrodes provided by the enclosure of the implantable device. According to a preferred embodiment of the invention, the implantable device has an enclosure, which is made from an electrically conductive and biocompatible material like titanium for example. In another preferred embodiment the implantable device is made of a conductive body covered with a non-conductive material. Preferably, the non-conductive enclosure has one or more holes that allow the conductive body to contact the surrounding tissue.

[0020] Using such an implantable device, the amplitudes of atrial signals is very low. Therefore, detection and evaluation of atrial signals is difficult. Therefore, in a preferred embodiment of the invention, ventricular signals are evaluated for detecting atrial arrhythmia, such as Atrial Fibrillation or Atrial Flutter, without knowledge of atrial events or atrial intervals. According to a preferred embodiment of the invention, the presence or absence of events such as AF is identified only by evaluating the ventricular intervals.

[0021] However, this device may be an implantable cardiac device, such as a pacemaker (especially without atrial electrodes), a defibrillator or a cardioverter.

[0022] A further objective of the invention is to provide a computer-readable storage medium as defined in claim 11.

[0023] The invention may be implemented in software, hardware or as a mixed-mode solution.

Fig. 1 is a schematic illustration of an embodiment of a method for detecting cardiac events;

Fig. 2 is a further schematic illustration of an alternative embodiment of a method for detecting cardiac events.

[0024] Figure 1 shows an example of a first embodiment of the method for detecting cardiac events. In this special embodiment a packet 100 of eight consecutive intervals is analyzed. The intervals of the packet 100 are stored in cells 101, 102, ..., 108. In step 110 of the analysis it is determined if cell #1 101 contains an interval. If there is detected an interval in cell #1 101 the analysis proceeds with step 112, where the Stability Limit is calculated. In a preferred embodiment the Stability Limit is calculated as a percentage of the of the average value of the intervals in the packet, where for detection of AF another percentage may be used than for detection of other cardiac events such as for detection of termination of AF for example. However, also the same percentage may be used for both, detection of AF and detection of termination of AF.

[0025] After determining the Stability Limit in step 112, in a loop 114 the seven differences between consecutive intervals for Int(i) (= 2, 3, ..., 8) in the packet are evaluated, and instability is indicated in step 116 if the following criterion is met:

> Absolute [Current Interval - Preceding Interval] > Stability Limit; AND
> Absolute [2 * Current Interval - Preceding Interval] > 2 * Stability Limit; AND
> Absolute [Current Interval - 2 * Preceding Interval] > 2 * Stability Limit.

[0026] In step 116 the instability counter is incremented by one each time this criterion is met for a pair from the eight consecutive intervals.

[0027] Then, in step 118 of this embodiment, the interval packet 100 is cleared. However, in other embodiments the interval packet 100 may be cleared later, for example in step 224 (see figure 2) after the instability counter has been compared with a AF Compare Limit, or in step 234 after the instability counter has been compared with a Termination Compare Limit.

[0028] In the next step 120 it is checked whether or not an AF status has been declared or not. When not in AF status, the analysis proceeds with step 122, where the value of the instability counter is compared with a pre-determined AF Compare Limit to decide whether presence of AF is indicated. Presence is indicated in step 122 if the value of the instability counter reaches or exceeds the AF Compare Limit. In this case, a packet counter, which is used in following steps of the analysis, is incremented in step 124.

[0029] After the packet counter is incremented in step 124, the packet counter is compared in step 128 with the value of a pre-determined AF Packet Hysteresis. Only if AF presence is indicated for a pre-determined number of consecutively analyzed packets, i.e. the packet counter has reached the value of the AF Packet Hysteresis, AF status is declared in step 130, and the packet counter is cleared.

[0030] When already in AF status, which is determined in step 120, the analysis proceeds with step 132, where the value of the instability counter is compared with a pre-determined Termination Compare Limit to decide whether absence of AF is indicated. Absence is indicated in step 132 if the value of the instability counter is equal to or less than the Termination Compare Limit. In this case, the packet counter is incremented in step 134.

[0031] After the packet counter is incremented in step 134, the packet counter is compared in step 136 with the value of a pre-determined Termination Packet Hysteresis. Only if AF absence is indicated for a pre-determined

number of consecutively analyzed packets, i.e. the packet counter has reached the value of the Termination Packet Hysteresis, termination of the AF is declared in step 138, and the packet counter is cleared.

[0032] If it is determined in step 122 that the value of the instability counter is less than the AF Compare Limit, the packet counter is cleared in step 126. Also, if it is determined in step 132 that the value of the instability counter is greater than the Termination Compare Limit, the packet counter is cleared in step 126.

Claims

1. A device for detecting cardiac events comprising control means and storage means and being programmed for performing the method comprising an analysis with the steps of:

(a) for an interval packet comprising a number of consecutive heart intervals calculating for at least a part of the consecutive heart intervals the difference between pairs of consecutive heart intervals;
(b) comparing the differences with at least one stability limit;
(c) calculating an instability counter depending from the result of the comparison in step (b);
(d) determining whether the cardiac event in the interval packet is indicated by comparing the value of the instability counter with a settable event compare count limit; and
(e) declaring the cardiac event if presence of the cardiac event is indicated in a pre-defined number of consecutive interval packets

characterised in that the calculation of the instability counter in step (c) is performed as follows:

the instability counter is incremented if:

- the absolute value of the difference between a current interval of the packet and the preceding interval of the packet is greater than the stability limit, and
- the absolute value of the difference between twice the current interval of the packet and the preceding interval of the packet is greater than twice the stability limit, and
- the absolute value of the difference between the current interval of the packet and twice the preceding interval of the packet is greater than twice the stability limit.

2. The device according to claim 1, where the cardiac event comprises Atrial Fibrillation, and where:

- step (d) comprises determining whether presence of Atrial Fibrillation in the interval packet is indicated by comparing the value of the instability counter with a pre-defined Atrial Fibrillation compare count limit; and
- step (e) comprises declaring Atrial Fibrillation if presence of Atrial Fibrillation is indicated in a pre-defined number of consecutive interval packets.

3. The device according to claim 1, where the cardiac event comprises termination of Atrial Fibrillation, and where:

- step (d) comprises determining whether absence of Atrial Fibrillation in the interval packet is indicated by comparing the value of the instability counter with a pre-defined termination compare count limit; and
- step (e) comprises declaring termination of Atrial Fibrillation if absence of Atrial Fibrillation is indicated in a pre-defined number of consecutive interval packets.

4. The device according to any one of claim 1 to 3, where the stability limit is calculated as a settable percentage of the average values of the intervals within the interval packet.

5. The device according to any one of claim 1 to 4, where at least one of differences and stability limit is weighted by 1 or 2.

6. The device according to any one of claim 1 to 5, where for a heart beat which is associated with noise or for a heart beat which is recognized as a Premature Ventricular Contraction at least one of the following steps are executed:

- the current heart interval and the following heart interval are excluded from analysis; and
- a new interval packet is created starting from the heart beat that follows the next heart beat.

7. The device according to any one of claim 2 to 5, where for a heart beat which is associated with noise or for a heart beat which is recognized as a Premature Ventricular Contraction, one of the following steps are executed:

- the current heart interval and the following heart interval are excluded from analysis; or
- the instability counter is decremented by 1 and the current heart interval and the following heart interval are excluded from analysis, where in the case the instability counter becomes 0, a new interval packet is created starting from the heart beat that follows the next heart beat; or
- the instability counter is cleared and a new in-

terval packet is created starting from the heart beat that follows the next heart beat.

8. The device according to any one of claim 3 to 5, where for a heart beat which is associated with noise or for a heart beat which is recognized as a Premature Ventricular Contraction, one of the following steps are executed:

- the current heart interval and the following heart interval are excluded from analysis; or
- the instability counter is incremented by 1 and the current heart interval and the following heart interval are excluded from analysis, where in the case the instability counter becomes equal to the termination compare count limit, the instability counter is cleared and a new interval packet is created starting from the heart beat that follows the next heart beat; or
- the instability counter is cleared and a new interval packet is created starting from the heart beat that follows the next heart beat.

9. The device according to any one of claim 1 to 8, where at least a part of the heart intervals are ventricular intervals, and wherein the device further comprises cardiac electrodes for detecting ventricular signals.

10. The device according to claim 9, where atrial arrhythmia is detected from the ventricular intervals.

11. A computer-readable storage medium storing program code for causing the data processing device according to any one of claims 1-10 to perform a method for detecting cardiac events, the method comprising an analysis with the steps of:

(a) for an interval packet comprising a number of consecutive heart intervals calculating for at least a part of the consecutive heart intervals the difference between pairs of consecutive heart intervals;
(b) comparing the differences with at least one stability limit;
(c) calculating an instability counter depending from the result of the comparison in step (b);
(d) determining whether the cardiac event in the interval packet is indicated by comparing the value of the instability counter with a settable event compare count limit; and
(e) declaring the cardiac event if presence of the cardiac event is indicated in a pre-defined number of consecutive interval packets

characterised in that the calculation of the instability counter in step (c) is performed as follows:

the instability counter is incremented if:

- the absolute value of the difference between a current interval of the packet and the preceding interval of the packet is greater than the stability limit, and
- the absolute value of the difference between twice the current interval of the packet and the preceding interval of the packet is greater than twice the stability limit, and
- the absolute value of the difference between the current interval of the packet and twice the preceding interval of the packet is greater than twice the stability limit.

Patentansprüche

1. Vorrichtung zur Erfassung von kardialen Ereignissen, das eine Steuereinrichtung und eine Speichereinrichtung umfasst und dafür programmiert ist, ein Verfahren durchzuführen, welches eine Analyse umfasst mit den folgenden Schritten:

(a) Berechnen der Differenz zwischen Paaren aus aufeinander folgenden Herzintervallen für zumindest einen Teil aufeinander folgender Herzintervalle eines Intervall-Pakets, das eine Anzahl von aufeinander folgenden Herzintervallen umfasst;
(b) Vergleichen der Differenzen mit mindestens einer Stabilitätsgrenze;
(c) Berechnen eines Instabilitätszählers abhängig vom Ergebnis des Vergleichs in Schritt (b);
(d) Bestimmen, ob das kardiale Ereignis im Intervall-Paket angezeigt wird, durch Vergleichen des Wertes des Instabilitätszählers mit einer einstellbaren Ereignisvergleichszählgrenze; und
(e) Deklarieren des kardialen Ereignisses, wenn das Vorliegen des kardialen Ereignisses in einer vordefinierten Anzahl von aufeinander folgenden Intervall-Paketen angezeigt wird,

dadurch gekennzeichnet, dass die Berechnung des Instabilitätszählers in Schritt (c) wie folgt durchgeführt wird:

der Instabilitätszähler wird hochgesetzt, wenn:

- der absolute Wert der Differenz zwischen einem aktuellen Intervall des Pakets und dem vorausgegangenen Intervall des Pakets über der Stabilitätsgrenze liegt, und
- der absolute Wert der Differenz zwischen dem Zweifachen des aktuellen Intervalls des Pakets und dem vorausgegangenen Intervall des Pakets über dem Zweifachen der

Stabilitätsgrenze liegt, und
- der absolute Wert der Differenz zwischen dem aktuellen Intervall des Pakets und dem Zweifachen des vorausgegangenen Intervalls des Pakets über dem Zweifachen der Stabilitätsgrenze liegt.

2. Vorrichtung nach Anspruch 1, wobei das kardiale Ereignis ein Vorhofflimmern umfasst, und wobei:

- Schritt (d) die Bestimmung umfasst, ob das Vorliegen eines Vorhofflimmerns im Intervall-Paket angezeigt wird, durch Vergleichen des Wertes des Instabilitätszählers mit einer vordefinierten Vorhofflimmern-Vergleichszählgrenze; und
- Schritt (e) das Deklarieren eines Vorhofflimmerns umfasst, wenn das Vorliegen eines Vorhofflimmerns in einer vordefinierten Anzahl von aufeinander folgenden Intervall-Paketen angezeigt wird.

3. Vorrichtung nach Anspruch 1, wobei das kardiale Ereignis ein Ende eines Vorhofflimmerns umfasst, und wobei:

- Schritt (d) eine Bestimmung umfasst, ob die Abwesenheit eines Vorhofflimmems im Intervall-Paket angezeigt wird, durch Vergleichen des Wertes des Instabilitätszählers mit einer vordefinierten Ende-Vergleichszählgrenze; und
- Schritt (e) das Deklarieren des Endes des Vorhofflimmerns umfasst, wenn das Fehlen eines Vorhofflimmerns in einer vordefinierten Anzahl von aufeinander folgenden Intervall-Paketen angezeigt wird.

4. Vorrichtung nach einem der Ansprüche 1 bis 3, wobei die Stabilitätsgrenze als einstellbarer Prozentanteil der Durchschnittswerte der Intervalle innerhalb des Intervall-Pakets berechnet wird.

5. Vorrichtung nach einem der Ansprüche 1 bis 4, wobei zumindest eine von den Differenzen und der Stabilitätsgrenze mit 1 oder 2 gewichtet wird.

6. Vorrichtung nach einem der Ansprüche 1 bis 5, wobei für einen Herzschlag, der mit einem Geräusch assoziiert ist, oder für einen Herzschlag, der als ventrikuläre Extrasystole erkannt wird, mindestens einer der folgenden Schritte durchgeführt wird:

- das aktuelle Herzintervall und das folgende Herzintervall werden aus der Analyse ausgeschlossen; und
- ein neues Intervall-Paket wird erzeugt, das mit dem Herzschlag beginnt, der auf den nächsten Herzschlag folgt.

7. Vorrichtung nach einem der Ansprüche 2 bis 5, wobei für einen Herzschlag, der mit einem Geräusch assoziiert ist, oder für einen Herzschlag, der als ventrikuläre Extrasystole erkannt wird, einer der folgenden Schritte durchgeführt wird:

- das aktuelle Herzintervall und das folgende Herzintervall werden von der Analyse ausgeschlossen; oder
- der Instabilitätszähler wird um 1 zurückgesetzt, und das aktuelle Herzintervall und das folgende Herzintervall werden von der Analyse ausgeschlossen, wobei in dem Fall, dass der Instabilitätszähler 0 wird, ein neues Intervall-Paket erzeugt wird, das mit dem Herzschlag beginnt, der auf den nächsten Herzschlag folgt; oder
- der Instabilitätszähler wird gelöscht und ein neues Intervall-Paket wird erzeugt, das mit dem Herzschlag beginnt, der auf den nächsten Herzschlag folgt.

8. Vorrichtung nach einem der Ansprüche 3 bis 5, wobei für einen Herzschlag, der mit einem Geräusch assoziiert ist, oder für einen Herzschlag, der als ventrikuläre Extrasystole erkannt wird, einer der folgenden Schritte durchgeführt wird:

- das aktuelle Herzintervall und das folgende Herzintervall werden von der Analyse ausgeschlossen; oder
- der Instabilitätszähler wird um 1 hochgezählt, und das aktuelle Herzintervall und das folgende Herzintervall werden von der Analyse ausgeschlossen, wobei in dem Fall, dass der Instabilitätszähler der Beendigungsvergleichs-Zählgrenze gleich wird, der Instabilitätszähler gelöscht wird und ein neues Intervall-Paket erzeugt wird, das ab dem Herzschlag beginnt, der auf den nächsten Herzschlag folgt; oder
- der Instabilitätszähler wird gelöscht und ein neues Intervall-Paket wird erzeugt, das ab dem Herzschlag beginnt, der auf den nächsten Herzschlag folgt.

9. Vorrichtung nach einem der Ansprüche 1 bis 8, wobei zumindest ein Teil der Herzintervalle ventrikuläre Intervalle sind, und wobei die Vorrichtung ferner kardiale Elektroden umfasst, um ventrikuläre Signale zu erfassen.

10. Vorrichtung nach Anspruch 9, wobei eine atriale Arrhythmie aus den ventrikulären Intervallen erfasst wird.

11. Computer-lesbares Speichermedium, das einen Programmcode speichert, der bewirkt, dass die Datenverarbeitungsvorrichtung gemäß den Ansprüche 1 bis 10 ein Verfahren zur Erfassung von kardialen

Ereignissen durchführt, wobei das Verfahren eine Analyse mit den folgenden Schritten umfasst:

(a) Berechnen der Differenz zwischen Paaren aus aufeinander folgenden Herzintervallen für zumindest einen Teil von aufeinander folgenden Herzintervallen eines Intervall-Pakets, das eine Anzahl von aufeinander folgenden Herzintervallen umfasst;
(b) Vergleichen der Differenzen mit mindestens einer Stabilitätsgrenze;
(c) Berechnen eines Instabilitätszählers abhängig vom Ergebnis des Vergleichs in Schritt (b);
(d) Bestimmen, ob das kardiale Ereignis im Intervall-Paket angezeigt wird, durch Vergleichen des Wertes des Instabilitätszählers mit einer einstellbaren Ereignisvergleichszählgrenze; und
(e) Deklarieren des kardialen Ereignisses, wenn das Vorliegen des kardialen Ereignisses in einer vordefinierten Anzahl von aufeinander folgenden Intervall-Paketen angezeigt wird,

dadurch gekennzeichnet, dass die Berechnung des Instabilitätszählers in Schritt (c) wie folgt durchgeführt wird:

der Instabilitätszähler wird hochgesetzt, wenn:

- der absolute Wert der Differenz zwischen einem aktuellen Intervall des Pakets und dem vorausgegangenen Intervall des Pakets über der Stabilitätsgrenze liegt, und
- der absolute Wert der Differenz zwischen dem Zweifachen des aktuellen Intervalls des Pakets und dem vorausgegangenen Intervall des Pakets über dem Zweifachen der Stabilitätsgrenze liegt, und
- der absolute Wert der Differenz zwischen dem aktuellen Intervall des Pakets und dem Zweifachen des vorausgegangenen Intervalls des Pakets über dem Zweifachen der Stabilitätsgrenze liegt.

Revendications

1. Dispositif pour la détection d'évènements cardiaques, comprenant un moyen de contrôle et un moyen de stockage et étant programmé pour exécuter le procédé comprenant une analyse, avec les étapes suivantes :

(a) pour un paquet d'intervalles comprenant un nombre d'intervalles cardiaques consécutifs, calcul, pour au moins une partie des intervalles cardiaques consécutifs, de la différence entre des paires d'intervalles cardiaques consécutifs ;
(b) comparaison des différences avec au moins une limite de stabilité ;
(c) calcul d'un compteur d'instabilité, en fonction du résultat de la comparaison dans l'étape (b) ;
(d) détermination de l'indication de l'évènement cardiaque dans le paquet d'intervalles, en comparant la valeur du compteur d'instabilité avec une limite de comptage de comparaison réglable ; et
(e) déclaration de l'évènement cardiaque si la présence de l'évènement cardiaque est indiquée dans un nombre prédéfini de paquets d'intervalles consécutifs,

caractérisé en ce que le calcul du compteur d'instabilité dans l'étape (c) est réalisé de la manière suivante :

le compteur d'instabilité est incrémenté si :

- la valeur absolue de la différence entre un intervalle actuel du paquet et l'intervalle précédent du paquet est supérieure à la limite de stabilité, et
- la valeur absolue de la différence entre deux fois l'intervalle actuel du paquet et l'intervalle précédent du paquet est supérieure à deux fois la limite de stabilité, et
- la valeur absolue de la différence entre l'intervalle actuel du paquet et deux fois l'intervalle précédent du paquet est supérieure à deux fois la limite de stabilité.

2. Dispositif selon la revendication 1, dans lequel l'évènement cardiaque comprend la Fibrillation Atriale, et dans lequel :

- l'étape (d) comprend la détermination de l'indication de la présence d'une Fibrillation Atriale dans le paquet d'intervalles, en comparant la valeur du compteur d'instabilité avec une limite prédéfinie de comptage de comparaison de Fibrillation Atriale ; et
- l'étape (e) comprend la déclaration d'une Fibrillation Atriale si la présence de Fibrillation Atriale est indiquée dans un nombre prédéfini de paquets d'intervalles consécutifs.

3. Dispositif selon la revendication 1, dans lequel l'évènement cardiaque comprend la fin de la Fibrillation Atriale, et dans lequel :

- l'étape (d) comprend la détermination de l'indication de l'absence de Fibrillation Atriale dans le paquet d'intervalles, en comparant la valeur du compteur d'instabilité avec une limite prédéfinie de comptage de comparaison de fin ; et
- l'étape (e) comprend la déclaration de la fin de

la Fibrillation Atriale si l'absence de Fibrillation Atriale est indiquée dans un nombre prédéfini de paquets d'intervalles consécutifs.

4. Dispositif selon l'une quelconque des revendications 1 à 3, dans lequel la limite de stabilité est calculée comme un pourcentage réglable des valeurs moyennes des intervalles compris dans le paquet d'intervalles.

5. Dispositif selon l'une quelconque des revendications 1 à 4, dans lequel au moins un élément parmi les différences et la limite de stabilité est pondéré par 1 ou 2.

6. Dispositif selon l'une quelconque des revendications 1 à 5, dans lequel, pour un battement de coeur associé à un bruit ou pour un battement de coeur reconnu comme une Contraction Ventriculaire Prématurée, au moins l'une des étapes suivantes est exécutée :

- l'intervalle cardiaque actuel et l'intervalle cardiaque suivant sont exclus de l'analyse ; et
- un nouveau paquet d'intervalles est créé à partir du battement de coeur consécutif au battement de coeur suivant.

7. Dispositif selon l'une quelconque des revendications 2 à 5, dans lequel, pour un battement de coeur associé à un bruit ou pour un battement de coeur reconnu comme une Contraction Ventriculaire Prématurée, au moins l'une des étapes suivantes est exécutée :

- l'intervalle cardiaque actuel et l'intervalle cardiaque suivant sont exclus de l'analyse ; ou
- le compteur d'instabilité est décrémenté de 1 et l'intervalle cardiaque actuel et l'intervalle cardiaque suivant sont exclus de l'analyse, où, dans le cas où le compteur d'instabilité tombe à zéro, un nouveau paquet d'intervalles est créé à partir du battement de coeur consécutif au battement de coeur suivant ; ou
- le compteur d'instabilité est remis à zéro et un nouveau paquet d'intervalles est créé à partir du battement de coeur consécutif au battement de coeur suivant.

8. Dispositif selon l'une quelconque des revendications 3 à 5, dans lequel, pour un battement de coeur associé à un bruit ou pour un battement de coeur reconnu comme une Contraction Ventriculaire Prématurée, l'une des étapes suivantes est exécutée :

- l'intervalle cardiaque actuel et l'intervalle cardiaque suivant sont exclus de l'analyse ; ou
- le compteur d'instabilité est incrémenté de 1 et l'intervalle cardiaque actuel et l'intervalle cardiaque suivant sont exclus de l'analyse, où, dans le cas où le compteur d'instabilité devient égal à la limite de comptage de comparaison de fin, le compteur d'instabilité est remis à zéro et un nouveau paquet d'intervalles est créé à partir du battement de coeur consécutif au battement de coeur suivant ; ou
- le compteur d'instabilité est remis à zéro et un nouveau paquet d'intervalles est créé à partir du battement de coeur consécutif au battement de coeur suivant.

9. Dispositif selon l'une quelconque des revendications 1 à 8, dans lequel au moins une partie des intervalles cardiaques sont des intervalles ventriculaires, et dans lequel le dispositif comprend en outre des électrodes cardiaques pour la détection de signaux ventriculaires.

10. Dispositif selon la revendication 9, dans lequel une arythmie atriale est détectée à partir des intervalles ventriculaires.

11. Support de stockage lisible par ordinateur stockant un code de programme destiné à inciter le dispositif de traitement de données selon l'une quelconque des revendications 1 - 10 à exécuter un procédé pour la détection d'évènements cardiaques, le procédé comprenant une analyse avec les étapes suivantes ;

(a) pour un paquet d'intervalles comprenant un nombre d'intervalles cardiaques consécutifs, calcul, pour au moins une partie des intervalles cardiaques consécutifs, de la différence entre des paires d'intervalles cardiaques consécutifs ;
(b) comparaison des différences avec au moins une limite de stabilité ;
(c) calcul d'un compteur d'instabilité, en fonction du résultat de la comparaison dans l'étape (b) ;
(d) détermination de l'indication de l'évènement cardiaque dans le paquet d'intervalles, en comparant la valeur du compteur d'instabilité avec une limite de comptage de comparaison réglable ; et
(e) déclaration de l'évènement cardiaque si la présence de l'évènement cardiaque est indiquée dans un nombre prédéfini de paquets d'intervalles consécutifs,

caractérisé en ce que le calcul du compteur d'instabilité dans l'étape (c) est réalisé de la manière suivante :

le compteur d'instabilité est incrémenté si :

- la valeur absolue de la différence entre un intervalle actuel du paquet et l'intervalle pré-

cédent du paquet est supérieure à la limite de stabilité, et

- la valeur absolue de la différence entre deux fois l'intervalle actuel du paquet et l'intervalle précédent du paquet est supérieure à deux fois la limite de stabilité, et
- la valeur absolue de la différence entre l'intervalle actuel du paquet et deux fois l'intervalle précédent du paquet est supérieure à deux fois la limite de stabilité.

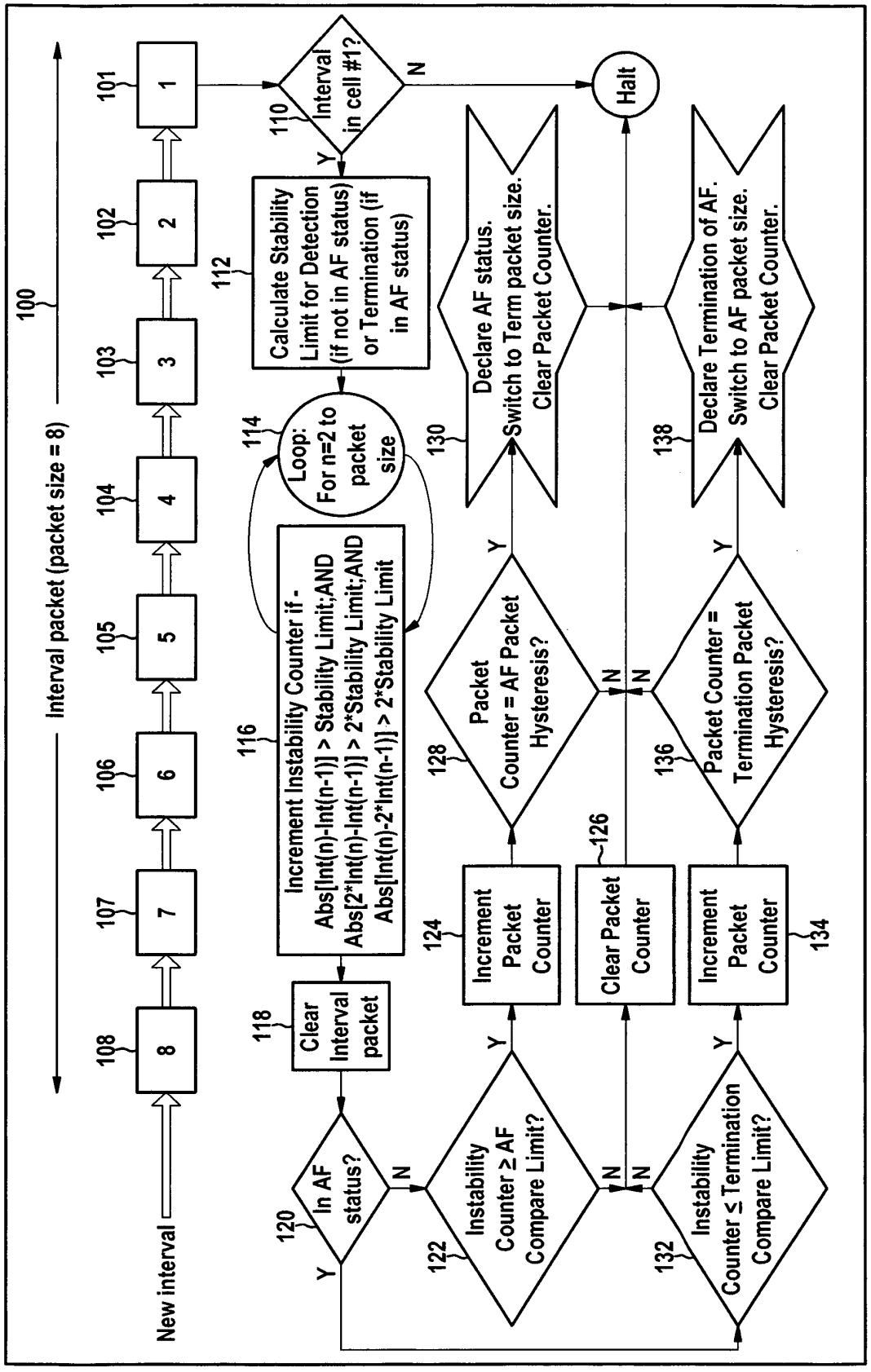
100
Interval packet (packet size = 8)
New interval
101
102
103
104
105
106
107
108
1
2
3
4
5
6
7
8
110
Interval in cell #1?
Y
N
Halt
112
Calculate Stability Limit for Detection (if not in AF status) or Termination (if in AF status)
114
Loop: For n=2 to packet size
116
Increment Instability Counter if - Abs[Int(n)-Int(n-1)] > Stability Limit;AND Abs[2*Int(n)-Int(n-1)] > 2*Stability Limit;AND Abs[Int(n)-2*Int(n-1)] > 2*Stability Limit
118
Clear Interval packet
120
In AF status?
122
Instability Counter ≥ AF Compare Limit?
124
Increment Packet Counter
126
Clear Packet Counter
128
Packet Counter = AF Packet Hysteresis?
130
Declare AF status. Switch to Term packet size. Clear Packet Counter.
132
Instability Counter ≤ Termination Compare Limit?
134
Increment Packet Counter
136
Packet Counter = Termination Packet Hysteresis?
138
Declare Termination of AF. Switch to AF packet size. Clear Packet Counter.

Fig. 1

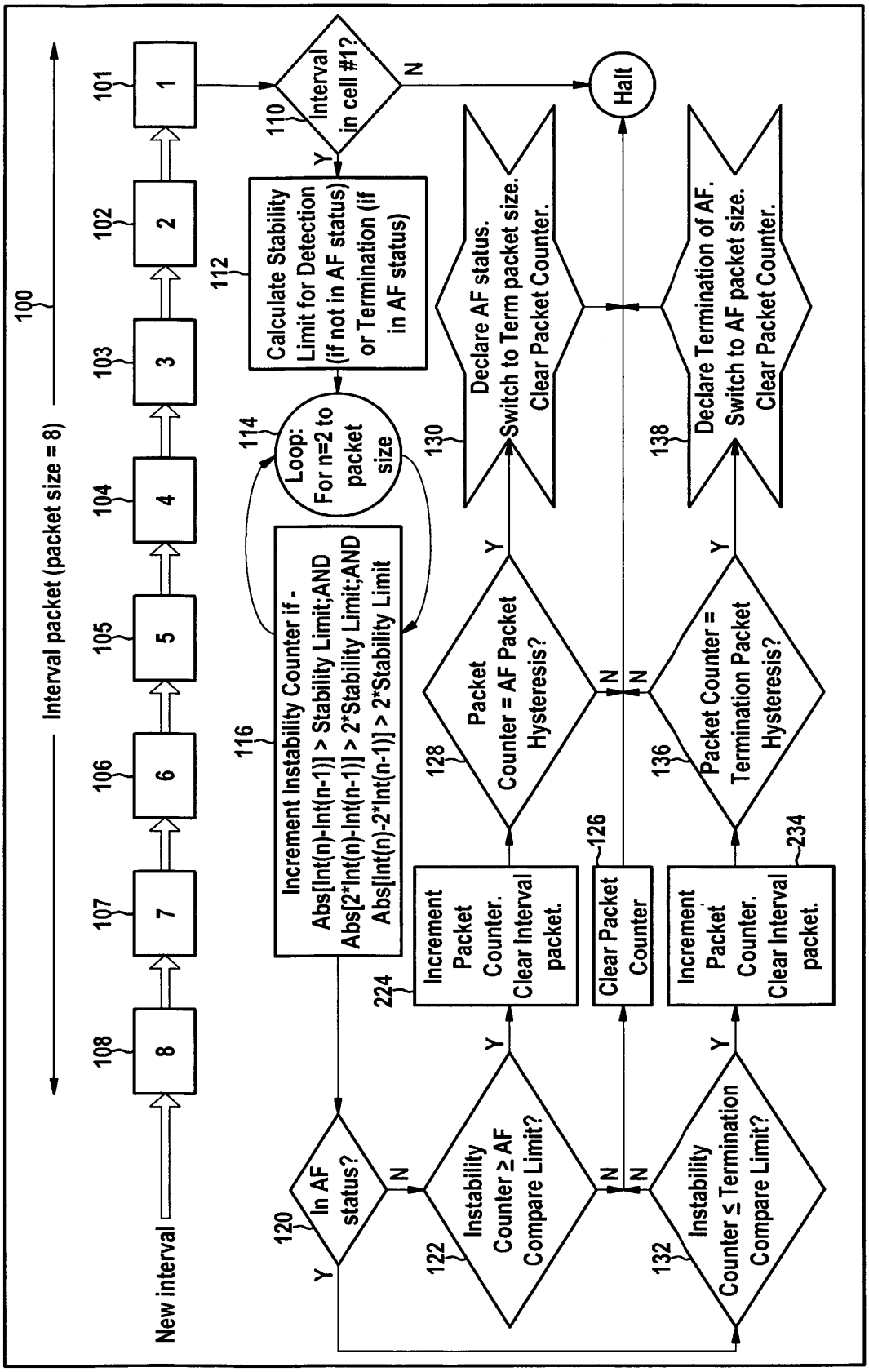
100
Interval packet (packet size = 8)
101
102
103
104
105
106
107
108
New interval
110
Interval in cell #1?
Y
N
Halt
112
Calculate Stability Limit for Detection (if not in AF status) or Termination (if in AF status)
114
Loop: For n=2 to packet size
116
Increment Instability Counter if - Abs[Int(n)-Int(n-1)] > Stability Limit;AND Abs[2*Int(n)-Int(n-1)] > 2*Stability Limit;AND Abs[Int(n)-2*Int(n-1)] > 2*Stability Limit
120
In AF status?
122
Instability Counter ≥ AF Compare Limit?
224
Increment Packet Counter. Clear Interval packet.
126
Clear Packet Counter
128
Packet Counter = AF Packet Hysteresis?
130
Declare AF status. Switch to Term packet size. Clear Packet Counter.
132
Instability Counter ≤ Termination Compare Limit?
234
Increment Packet Counter. Clear Interval packet.
136
Packet Counter = Termination Packet Hysteresis?
138
Declare Termination of AF. Switch to AF packet size. Clear Packet Counter.

Fig. 2

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 4880005 A **[0002]**
- WO 02056961 A2 **[0002]**
- US 6671548 B1 **[0003]**

专利名称(译)	用于检测和分类心脏事件的设备和计算机可读存储介质		
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优先权	12/254728 2008-10-20 US		
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摘要(译)

本发明的一个方面是提供一种用于检测心脏事件的方法，例如心房纤颤（AF）或AF的终止。该方法基于对心率中观察到的不稳定性的分析，已知该不稳定性是由AF发作期间来自心房的不规则传导引起的。在逐个心跳的基础上监测心脏间隔的变化，以试图识别指示存在心房纤颤或心房颤动的不稳定性。根据本发明方法的第一步骤，评估多个连续间隔的分组，无论间隔的长度与前一间隔的长度相比是否稳定，或者后续间隔的长度是否已经改变。在检测到不稳定性之后，不稳定计数器递增。间隔包的稳定性测试的结果由不稳定性计数器的值表示。取决于是否已经宣布心房纤颤（AF），其由AF状态标志指示，应用不同的“X-out-of-Y”标准。在声明AF或分别声明AF终止时，设置或清除AF状态标志。