(19) Europäisches Patentamt
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(11) **EP 2 177 157 A1**

(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:
21.04.2010 Bulletin 2010/16

(51) Int Cl.:
A61B 5/046 *(2006.01)*

(21) Application number: **09172863.4**

(22) Date of filing: **13.10.2009**

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO SE SI SK SM TR

(30) Priority: **20.10.2008 US 254728**

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

(57) One aspect of the invention is to provide 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 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, an instability counter is incremented. 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 Fibrillation (AF) is already 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.

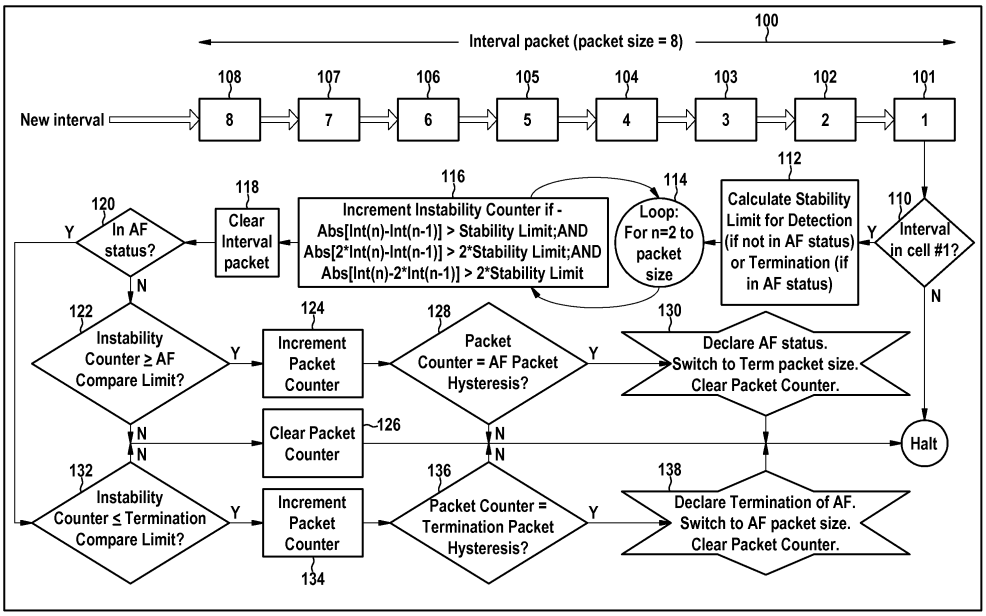

Fig. 1

EP 2 177 157 A1

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 method and device for detecting Atrial Fibrillation or Atrial Flutter by evaluating ventricular signals. Further, the present invention relates to 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. 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, the method comprising the following steps:

[0005] One aspect of the invention is to provide 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 inventive 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 inventive method an instability counter is calculated depending from the result of the comparison of the differences with the pre-determined stability limit. According to a preferred embodiment of 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] According to the invention a predetermined event packet hysteresis is 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:

[0015] Noise options:

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.

[0016] PVC options:

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 inventive 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 Fibrillation (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] It is a further objective of the invention to provide a device for detecting cardiac events comprising control and storage means, the device being arranged for executing 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.

[0020] According to a preferred embodiment of the invention the implantable device is realized as a pure monitoring device, which does not stimulate the heart. In contrary to the prior art, such an inventive implantable device do 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.

[0021] 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.

[0022] However, this device may be an implantable cardiac device, such as a pacemaker (especially without atrial electrodes), a defibrillator or a cardioverter.

[0023] A further objective of the invention is to provide a computer-readable storage medium storing program code for causing a data processing device 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 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.

[0024] 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.

[0025] 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.

[0026] 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.

[0027] In step 116 the instability counter is increment-

ed by one each time this criterion is met for a pair from the eight consecutive intervals.

[0028] 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.

[0029] 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.

[0030] 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.

[0031] 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.

[0032] 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.

[0033] 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 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.

2. The method 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 method 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 method 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 method 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 method according to any one of claim 1 to 5, where in step (c) calculation of the instability counter is performed as follows:

   the instability counter is incremented if:

   - the absolute value of the difference be-

tween 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.

7. The method according to any one of claim 1 to 6, 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.

8. The method according to any one of claim 2 to 6, 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 interval packet is created starting from the heart beat that follows the next heart beat.

9. The method according to any one of claim 3 to 6, 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.

10. The method according to any one of claim 1 to 9, where at least a part of the heart intervals are ventricular intervals.

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

12. A device 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.

13. The device according to claim 12, where the device comprises an enclosure of electrically conductive or of electrically non-conductive material.

14. The device according to claim 13, where the electrically non-conductive material covers an electrically conductive body, the electrically non-conductive enclosure having one or more holes that allow the conductive body to contact surrounding tissue.

15. A computer-readable storage medium storing program code for causing a data processing device 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.

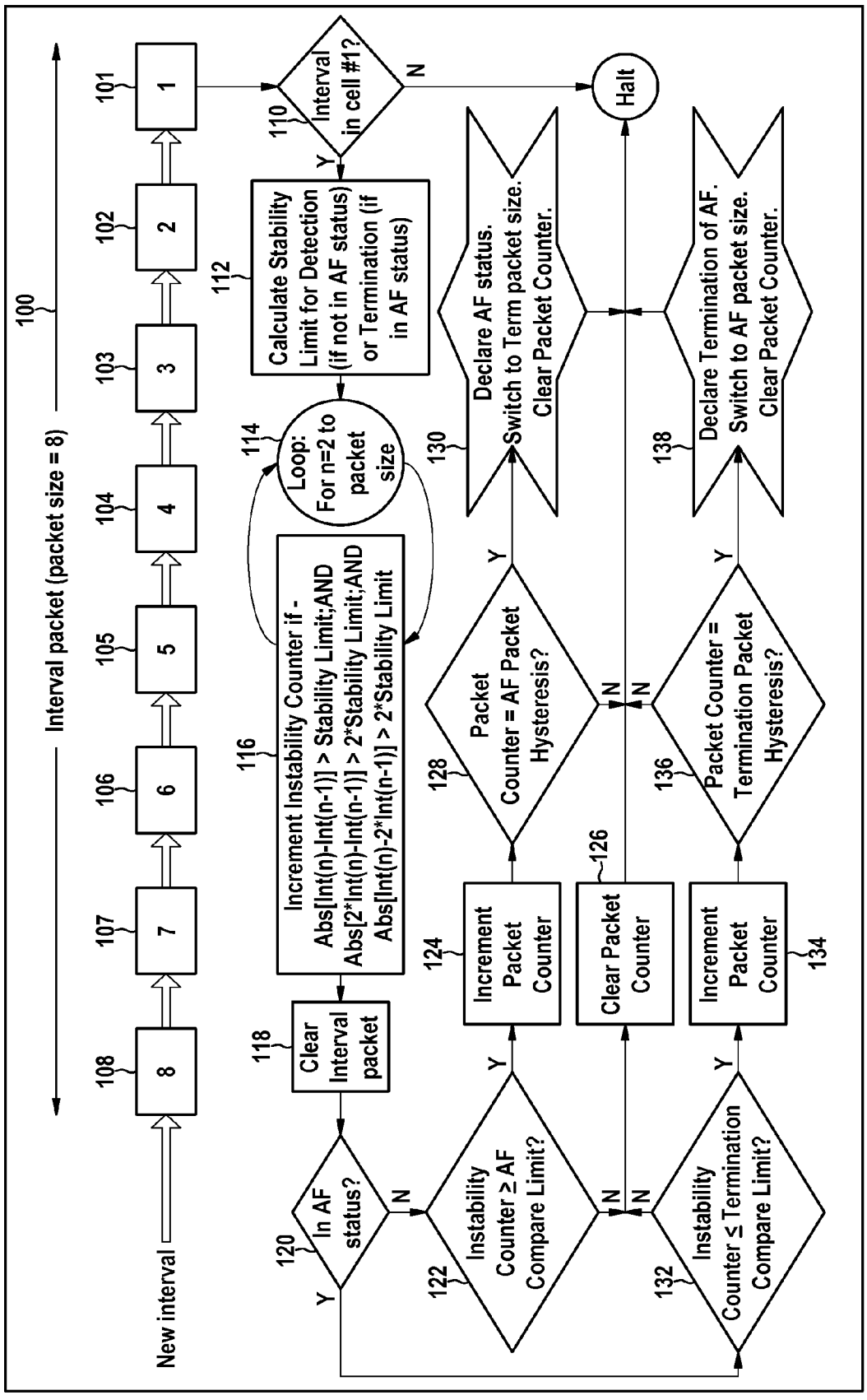
100
Interval packet (packet size = 8)
New interval
101
102
103
104
105
106
107
108
1
2
3
4
5
6
7
8
110
Interval in cell #1?
Y
N
Halt
112
Calculate Stability Limit for Detection (if not in AF status) or Termination (if in AF status)
114
Loop: For n=2 to packet size
116
Increment Instability Counter if - 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

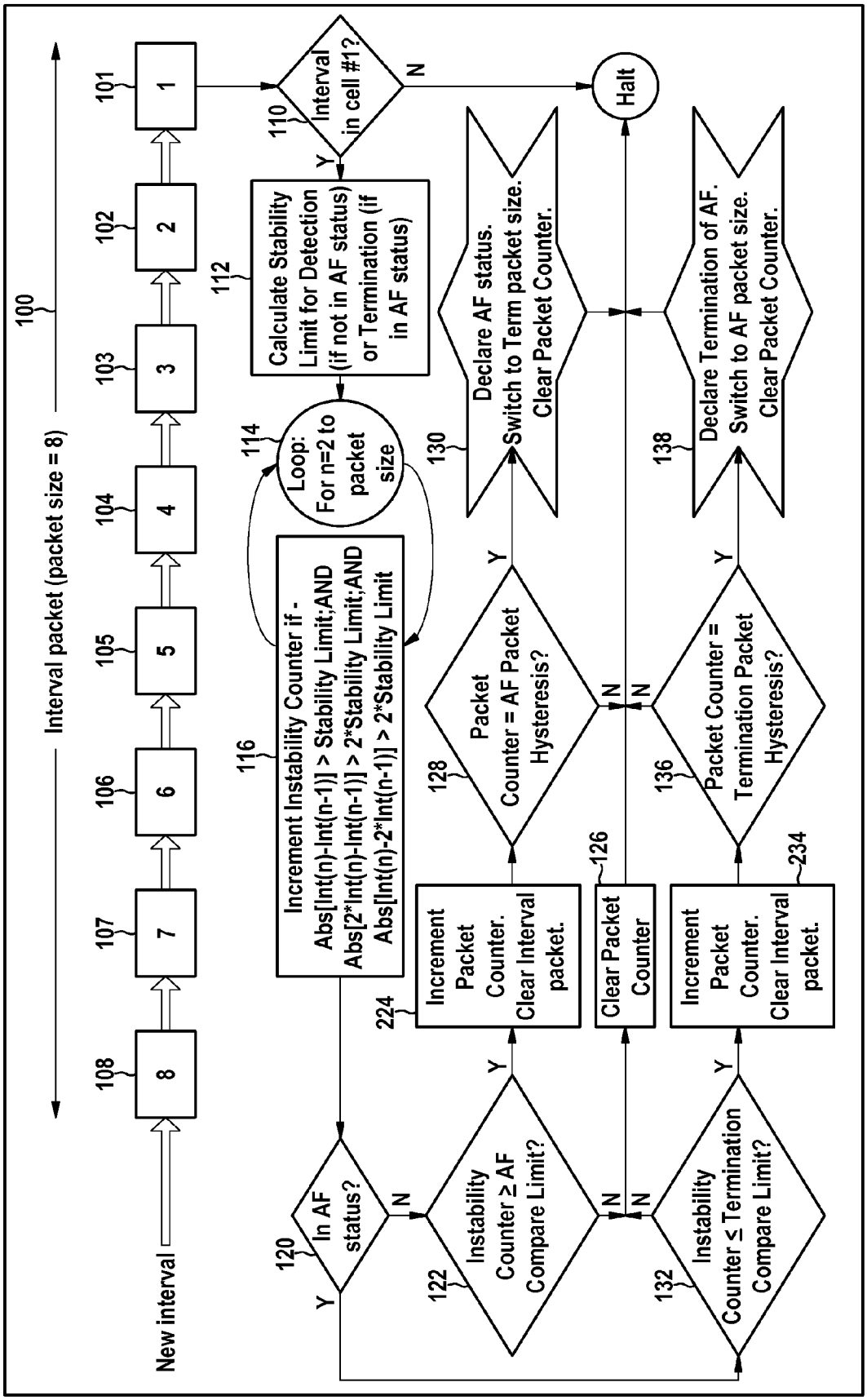
100
Interval packet (packet size = 8)
New interval
101
102
103
104
105
106
107
108
1
2
3
4
5
6
7
8
110
Interval in cell #1?
Y
N
Halt
112
Calculate Stability Limit for Detection (if not in AF status) or Termination (if in AF status)
114
Loop: For n=2 to packet size
116
Increment Instability Counter if - 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
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

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PARTIAL EUROPEAN SEARCH REPORT

which under Rule 63 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 09 17 2863

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 4 880 005 A (PLESS BENJAMIN D [US] ET AL) 14 November 1989 (1989-11-14) * column 4, line 8 - column 10, line 10 *	12-15	INV. A61B5/046
X,D	US 6 671 548 B1 (MOUCHAWAR GABRIEL A [US] ET AL) 30 December 2003 (2003-12-30) * the whole document *	12-15	
X	WO 02/056961 A (MEDTRONIC INC [US]) 25 July 2002 (2002-07-25) * the whole document *	12-15	
X	US 5 462 060 A (JACOBSON PETER [FR] ET AL) 31 October 1995 (1995-10-31) * the whole document *	12-15	

TECHNICAL FIELDS SEARCHED (IPC)

A61B

INCOMPLETE SEARCH

The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.

Claims searched completely :

Claims searched incompletely :

Claims not searched :

Reason for the limitation of the search:

see sheet C

Place of search	Date of completion of the search	Examiner
Munich	12 January 2010	Schöffmann

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04E07)

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INCOMPLETE SEARCH SHEET C

Application Number
EP 09 17 2863

Claim(s) not searched:
1-11

Reason for the limitation of the search (non-patentable invention(s)):

Article 53 (c) EPC - Diagnostic method practised on the human or animal body

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 09 17 2863

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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12-01-2010

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4880005 A	14-11-1989	CA 1290813 C	15-10-1991
US 6671548 B1	30-12-2003	DE 60026477 T2	14-09-2006
		EP 1112756 A2	04-07-2001
WO 02056961 A	25-07-2002	CA 2430172 A1	25-07-2002
		DE 60102836 D1	19-05-2004
		DE 60102836 T2	21-04-2005
		EP 1339453 A2	03-09-2003
		JP 4119751 B2	16-07-2008
		JP 2004517677 T	17-06-2004
US 5462060 A	31-10-1995	DE 69419822 D1	09-09-1999
		DE 69419822 T2	05-01-2000
		EP 0626182 A1	30-11-1994
		ES 2134911 T3	16-10-1999
		FR 2705576 A1	02-12-1994
		JP 7148129 A	13-06-1995

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REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 6671548 B1 **[0003]**

专利名称(译)	用于检测和分类心脏事件的设备，方法和计算机可读存储介质		
公开(公告)号	EP2177157A1	公开(公告)日	2010-04-21
申请号	EP2009172863	申请日	2009-10-13
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IPC分类号	A61B5/046 A61B5/00 A61B5/042 A61B5/0468 A61N1/37 A61N1/39		
CPC分类号	A61N1/3704 A61B5/042 A61B5/046 A61B5/0468 A61B5/6846 A61N1/395		
优先权	12/254728 2008-10-20 US		
其他公开文献	EP2177157B1		
外部链接	Espacenet		

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。

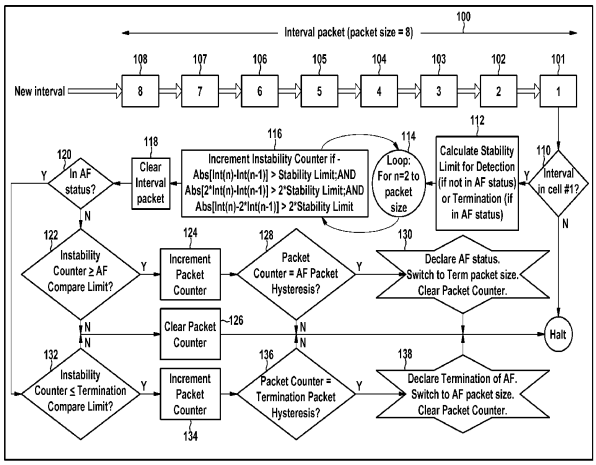

Fig. 1