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- (71) Applicant (for all designated States except US):
CAMERON HEALTH, INC. [US/US]; 905 Calle Amanecer, Suite 300, San Clemente, CA 92673 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **ALLAVATAM, Venugopal** [IN/US]; 4034 Craven Road, #32, Oceanside,

CA 92057 (US). **PALREDDY, Surekha** [US/US]; 2415 Nebraska Ave E, Maplewood, ME 55119 (US). **WARREN, Jay, A.** [US/US]; 30727 Paseo Elegancia, San Juan Capistrano, CA 92675 (US). **SANGHERA, Rick** [US/US]; 2901 Bonanza, San Clemente, CA 92673 (US).

- (74) Agent: **PRAMUDJI, Ari**; Pramudji, Wendt, And Tran, 1800 Bering Drive, Suite 540, Houston, TX 77057 (US).
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(54) Title: METHODS AND DEVICES FOR ACCURATELY CLASSIFYING CARDIAC ACTIVITY

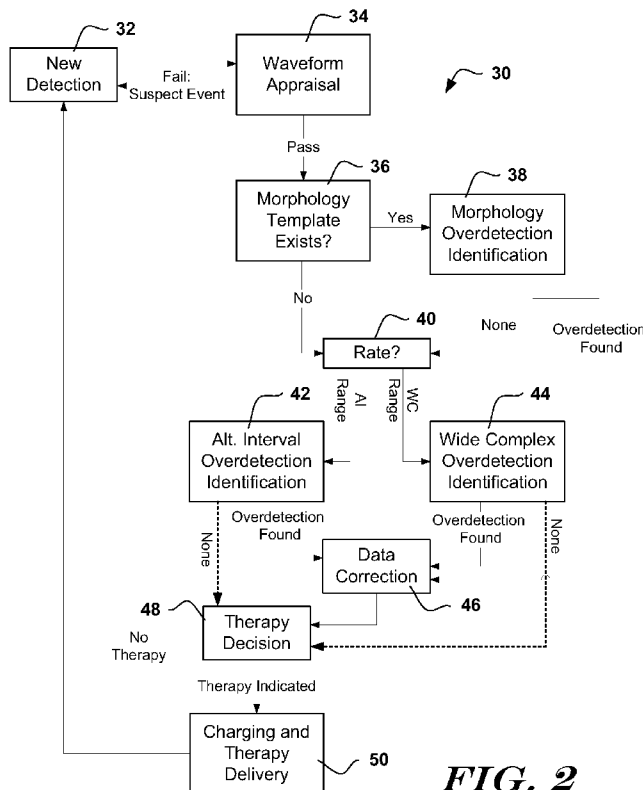


FIG. 2

(57) Abstract: Methods, systems, and devices for signal analysis in an implanted cardiac monitoring and treatment device such as an implantable cardioverter defibrillator. In illustrative examples, captured data including detected events is analyzed to identify likely overdetection of cardiac events. In some illustrative examples, when overdetection is identified, data may be modified to correct for overdetection, to reduce the impact of overdetection, or to ignore overdetection. New methods for organizing the use of morphology and rate analysis in an overall architecture for rhythm classification and cardiac signal analysis are also discussed.

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— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 7 330 757 B2 (OSTROFF ALAN H [US] ET AL) 12 February 2008 (2008-02-12) cited in the application column 9, line 45 - line 48 column 27, line 58 - line 60 column 28, line 5 - line 8 -----	1-4, 8-13, 17-19
A	US 2006/235476 A1 (GUNDERSON BRUCE D [US] ET AL) 19 October 2006 (2006-10-19) paragraph [0035] - paragraph [0088] -----	1-4, 8-13, 17-19
A	WO 2004/105871 A (CAMERON HEALTH INC [US]; OSTROFF ALAN H [US]; WARREN JAY A [US]; BARDY) 9 December 2004 (2004-12-09) page 13, line 1 - line 14 page 34, line 5 - line 25 -----	1-4, 8-13, 17-19

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

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European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040.
Fax: (+31-70) 340-3016

Authorized officer

Sopelana Martínez, J

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/036434

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 20-21
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
1-4, 8-13, 17-19
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-4

An implantable cardiac stimulus device (ICSD) comprising a canister housing operational circuitry and a lead assembly including a plurality of electrodes. The operational circuitry configured to perform a method of cardiac signal analysis comprising: Detecting a series of events, analysing a detection interval between consecutive events and comparing it to a wide-complex (WC) detection interval threshold. If the detection interval is less than the WC detection interval threshold, observing whether at least one of the following is also true: a) The consecutive detected events differ in polarity, b) an interval between the latter of the minimum or the maximum amplitude point for the first-in-time detected event and the first of the minimum or maximum amplitude point for the second-in-time detected event is less than an event peak threshold. If either a) or b) is true, the operational circuitry determines that one of the consecutive detected events is due to overdetecting.

2. claims: 5-7

An implantable cardiac stimulus device (ICSD) comprising a canister housing operational circuitry and a lead assembly including a plurality of electrodes. The operational circuitry configured to perform a method of cardiac signal analysis comprising: Detecting a series of events, identifying intervals between consecutive detected events, marking individual detected events as either true or false based upon a set of rules directed at identifying overdetections, determining whether a pattern of over-detection has been identified and: If so, discarding detected events marked as false and combining intervals on either side of discarded events into combined intervals; if not, marking false detected events as suspect. Performing rate analysis using combined intervals and intervals between consecutive true events. Using the rate analysis to determine whether a high cardiac rate condition needing therapy is likely occurring.

3. claims: 8-13

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

An implantable cardiac stimulus device (ICSD) comprising a canister housing operational circuitry and a lead assembly including a plurality of electrodes. The operational circuitry configured to perform a method of cardiac signal analysis comprising: Detecting a series of events, identifying intervals between consecutive detected events, using morphology analysis to identify overdetections, whenever an overdetection is identified, combining an interval preceding the overdetection and an interval following the overdetection to form a combined interval, following the morphology analysis to identify overdetections, estimating a cardiac rate using only certified intervals, and using the estimated cardiac rate to make therapy decisions.

4. claims: 14-15

An implantable cardiac stimulus device (ICSD) comprising a canister housing operational circuitry and a lead assembly including a plurality of electrodes. The operational circuitry configured to perform a method of cardiac signal analysis comprising: Detecting a series of events, comparing the detected events to a morphology template to establish a series of correlation scores indicative of the extent of correlation between the shape of the detected events and the morphology template, analysing the series of correlation scores to observe a high-low-high pattern, where the high-low-high pattern is identified, determining that the second-most recent event is an overdetection, upon finding an overdetection, combining an interval preceding the overdetection and an interval following the overdetection into a combined interval, using the combined interval in estimating cardiac rate, and using the estimated cardiac rate to make therapy decision.

5. claim: 16

An implantable cardiac stimulus device (ICSD) comprising a canister housing operational circuitry and a lead assembly including a plurality of electrodes. The operational circuitry configured to perform a method of cardiac signal analysis comprising: Detecting a series of events having raw intervals therebetween, analysing the series of events and raw intervals to determine whether individual events and intervals can be certified as not indicating noise or overdetection, using a set of certified intervals to estimate an average certified interval, using the certified interval to determine whether a treatable high-rate condition exists.

6. claims: 17-19

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

An implantable cardiac stimulus device (ICSD) comprising a canister housing operational circuitry and a lead assembly including a plurality of electrodes. The operational circuitry configured to perform a method of cardiac signal analysis comprising: Receiving signals from the electrodes, comparing the receiving signals to a detection threshold and identifying crossings of the detection threshold by the receiving signals as raw detected events, performing waveform analysis on a raw event to determine whether it results from or is masked by noise, performing overdetection analysis, certifying an interval between two detected events for use in rate calculation, and using certified intervals to calculate a rate of cardiac events for the purpose of identifying treatable cardiac conditions.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/US2009/036434
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 7330757	B2	US 2004254613 A1	16-12-2004
US 2006235476	A1	CA 2605167 A1	26-10-2006
		EP 1877137 A1	16-01-2008
		JP 2008536633 T	11-09-2008
		WO 2006113698 A1	26-10-2006
WO 2004105871	A	AT 413903 T	15-11-2008
		AU 2004242990 A1	09-12-2004
		CA 2526844 A1	09-12-2004
		CN 1829554 A	06-09-2006
		EP 1631352 A1	08-03-2006
		EP 2025363 A2	18-02-2009
		JP 2007501099 T	25-01-2007
		US 2008132965 A1	05-06-2008
		US 2009054938 A1	26-02-2009