(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 308 555 A3

(12) EUROPEAN PATENT APPLICATION

(88) Date of publication A3:
07.12.2011 Bulletin 2011/49

(43) Date of publication A2:
13.04.2011 Bulletin 2011/15

(21) Application number: **10001990.0**

(22) Date of filing: **25.01.2006**

(51) Int Cl.:
A61N 1/362 *(2006.01)* ***A61N 1/368*** *(2006.01)*
A61B 5/0468 *(2006.01)* ***A61N 1/365*** *(2006.01)*
A61N 1/39 *(2006.01)* ***A61B 5/0452*** *(2006.01)*
A61M 5/142 *(2006.01)* *A61B 5/00* *(2006.01)*
A61B 5/145 *(2006.01)*

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI SK TR

(30) Priority: **25.01.2005 US 43612**
25.01.2005 US 43780
25.01.2005 US 43804
11.05.2005 US 127370

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
06719544.6 / 1 850 909

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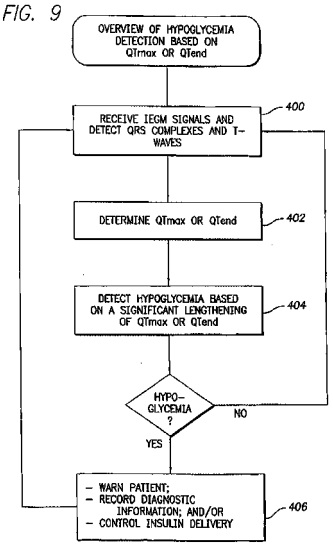
(54) System for detecting hypoglycemia, hyperglycemia and cardiac ischemia

(57) Techniques are described for detecting and distinguishing among ischemia, hypoglycaemia or hyperglycemia based on intracardiac electrogram (IEGM) signals. In one technique, these conditions are detected and distinguished based on an analysis of: the interval between the QRS complex and the peak of a T-wave (QTmax), the interval between the QRS complex and the end of a T-wave (QTend), alone or in combination with a change in ST segment elevation. By exploiting QTmax and QTend in combination with ST segment elevation, changes in ST segment elevation caused by hypo/hyperglycemia can be properly distinguished from changes caused by cardiac ischemia. In another technique, hyperglycemia and hypoglycaemia are predicted, detected and/or distinguished from one another based on an analysis of the amplitudes of P-waves, QRS-complexes and T-waves within the IEGM. Appropriate warning signals are delivered and therapy is automatically adjusted.

FIG. 9



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EUROPEAN SEARCH REPORT

Application Number
EP 10 00 1990

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	EP 1 419 731 A (PACESETTER, INC) 19 May 2004 (2004-05-19) * the whole document *	1-15	INV. A61N1/362 A61N1/368 A61B5/0468 A61N1/365 A61N1/39 A61B5/0452 A61M5/142 ADD. A61B5/00 A61B5/145
A	US 5 792 065 A (XUE ET AL) 11 August 1998 (1998-08-11) * the whole document *	1-15	
A	HARRIS N D ET AL: "Can changes in QT interval be used to predict the onset of hypoglycemia in type 1 diabetes?", COMPUTERS IN CARDIOLOGY 2000 CAMBRIDGE, MA, USA 24-27 SEPT. 2000, PISCATAWAY, NJ, USA,IEEE, US, 24 September 2000 (2000-09-24), pages 375-378, XP010528576, ISBN: 0-7803-6557-7 * the whole document *	1-15	
A	RANA BUSHRA S ET AL: "Relation of QT interval dispersion to the number of different cardiac abnormalities in diabetes mellitus.", THE AMERICAN JOURNAL OF CARDIOLOGY. 1 SEP 2002, vol. 90, no. 5, 1 September 2002 (2002-09-01), pages 483-487, XP002383130, ISSN: 0002-9149 * the whole document *	1-15	TECHNICAL FIELDS SEARCHED (IPC) A61N A61B A61M
A	EP 0 867 146 A (PACESETTER AB; ST. JUDE MEDICAL AB) 30 September 1998 (1998-09-30) * the whole document *	1-15	
A	EP 0 472 411 A (TELECTRONICS N.V) 26 February 1992 (1992-02-26) * the whole document *	1-15	

-/--

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	25 October 2011	Gentil, Cédric

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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EPO FORM 1503 03.82 (P04C01)

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EUROPEAN SEARCH REPORT

Application Number
EP 10 00 1990

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	OKIN PETER M ET AL: "Electrocardiographic repolarization complexity and abnormality predict all-cause and cardiovascular mortality in diabetes: the strong heart study.", DIABETES. FEB 2004, vol. 53, no. 2, February 2004 (2004-02), pages 434-440, XP002383131, ISSN: 0012-1797 * the whole document * -----	1-15	
			TECHNICAL FIELDS SEARCHED (IPC)

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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 10 00 1990

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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25-10-2011

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1419731 A	19-05-2004	DE 60303758 T2	31-08-2006
		US 2004077962 A1	22-04-2004
		US 2004078065 A1	22-04-2004
		US 2006100494 A1	11-05-2006
US 5792065 A	11-08-1998	NONE	
EP 0867146 A	30-09-1998	DE 69821663 D1	25-03-2004
		DE 69821663 T2	23-12-2004
		JP 10263094 A	06-10-1998
		US 6016443 A	18-01-2000
EP 0472411 A	26-02-1992	US 5113869 A	19-05-1992

EPO FORM P0459

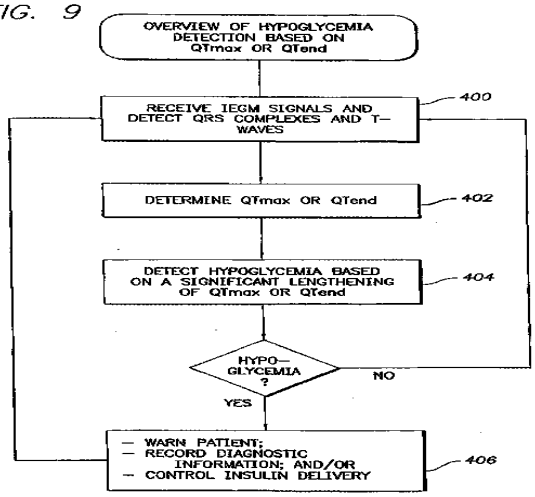
For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

专利名称(译)	用于检测低血糖，高血糖和心肌缺血的系统		
公开(公告)号	EP2308555A3	公开(公告)日	2011-12-07
申请号	EP2010001990	申请日	2006-01-25
[标]申请(专利权)人(译)	标兵		
申请(专利权)人(译)	PACESETTER，INC.		
当前申请(专利权)人(译)	PACESETTER，INC.		
[标]发明人	GILL JONG BOILEAU PETER BHARMI RUPINDER MIN XIAOYI FLORIO JOSEPH J BENSER MICHAEL BORNZIN GENE A		
发明人	GILL, JONG BOILEAU, PETER BHARMI, RUPINDER MIN, XIAOYI FLORIO, JOSEPH, J. BENSER, MICHAEL BORNZIN, GENE, A.		
IPC分类号	A61N1/362 A61N1/368 A61B5/0468 A61N1/365 A61N1/39 A61B5/0452 A61M5/142 A61B5/00 A61B5/145		
CPC分类号	A61B5/0452 A61B5/0468 A61B5/14532 A61N1/3621 A61N1/3627 A61N1/36557 A61N1/3925 A61N1/3962 A61N1/39622		
优先权	11/043612 2005-01-25 US 11/043780 2005-01-25 US 11/043804 2005-01-25 US 11/127370 2005-05-11 US		
其他公开文献	EP2308555A2 EP2308555B1		
外部链接	Espacenet		

摘要(译)

描述了用于基于心内电描记图（IEGM）信号检测和区分缺血，低血糖或高血糖的技术。在一种技术中，基于以下分析来检测和区分这些条件：QRS复合波与T波的峰值之间的间隔（QT-max），QRS波群与T波的结束之间的间隔（QTend），单独或与ST段抬高的变化组合。通过利用QTmax和QTend结合ST段抬高，由低血糖/高血糖引起的ST段抬高的变化可以适当地区别于由心脏缺血引起的变化。在另一种技术中，基于IEGM内的P波，QRS复合波和T波的幅度的分析，预测，检测和/或彼此区分高血糖和低血糖。提供适当的警告信号，并自动调整治疗。

FIG. 9


OVERVIEW OF HYPOGLYCEMIA DETECTION BASED ON QTmax OR QTend
RECEIVE IEGM SIGNALS AND DETECT QRS COMPLEXES AND T-WAVES
400
DETERMINE QTmax OR QTend
402
DETECT HYPOGLYCEMIA BASED ON A SIGNIFICANT LENGTHENING OF QTmax OR QTend
404
HYPO-GLYCEMIA ?
NO
YES
- WARN PATIENT;
- RECORD DIAGNOSTIC INFORMATION; AND/OR
- CONTROL INSULIN DELIVERY
406