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D E C I S I O N
of 27 September 2001

Case Number: T 0171/97 - 3.4.1

Application Number: 91916954.0

Publication Number: 0543939

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:
OPTIMIZATION FOR RATE RESPONSIVE CARDIAC PACEMAKER

Patentee:
MEDTRONIC, INC.

Opponent:
BIOTRONIK Mess- und Therapiegeräte GmbH & Co Ingenieurbüro Berlin

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (yes) - after amendment."

Decisions cited:
-

Catchword:
-

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Case Number: T 0171/97 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 27 September 2001

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 3 December 1996 revoking European patent No. 0 543 939 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: G. Davies
Members: M. G. L. Rognoni
G. Assi

Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal, received on 12 February 1997, against the decision of the opposition division, despatched on 3 December 1996, revoking the European patent No. 543 939. The fee for the appeal was paid on 12 February 1997 and the statement setting out the grounds of appeal was received on 14 April 1997.

II. The opposition had been filed against the patent as a whole, based on Articles 100(a), (b) and (c) EPC.

III. In the decision under appeal, the opposition division held, *inter alia*, that a pacemaker as specified in claims 1 and 2 of the granted patent did not involve an inventive step having regard to the following document:

D2: US-A-4 867 162.

IV. By letter dated 6 May 1997 the respondent (opponent) withdrew the opposition.

V. Oral proceedings were held on 27 September 2001.

VI. The appellant requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of:

Claims: No. 1 to 3 filed during the oral proceedings;

Description: pages 2 and 3 filed during the oral proceedings;

pages 4 to 18 (line 4) of the patent specification;

Drawings: 1/5 to 4/5 of the patent specification;
5/5 filed during the oral proceedings.

VII. The wording of claim 1 reads as follows:

"1. A rate responsive cardiac pacemaker (100) for providing an optimized pacing rate of stimulation pulses as a function of at least one selected rate control parameter, the or each of said rate control parameters having a value which varies as a function of changes in a patient's physiological demand, comprising:

A) one or more sensor means (S_1, S_2) for sensing the or each of said rate control parameter values and for providing a sensor output (RCP) representative thereof;

B) control means (114) coupled to the or each of said sensor means (S_1, S_2), comprising:

1) rate response defining means for deriving a desired pacing rate for the or each of said sensor outputs, thereby defining a predetermined rate response function for the or each of said sensor outputs which correlates the or each sensor output with a correspondingly desired pacing rate, such that for a predetermined change in sensor output a corresponding change in desired pacing rate is provided;

2) achievement monitoring means having a predetermined achievement criterion for the or each of

said sensor outputs which is reflective of desired pacing rates to be achieved for expected levels of exercise of said patient over a predetermined optimization period, said achievement criterion comprising, for the or each of said sensor outputs, a pacing rate component and a duration component, the pacing rate component being a preselected rate and the duration component being a minimum time interval over which the desired pacing rate must exceed the preselected rate, said achievement monitoring means monitoring the number of times the or each of said derived desired pacing rates exceeds said rate component for more than said duration component, within said optimisation period, and for providing an achievement output indicative of this number;

3) rate response control means for adjusting the or each of said rate response functions, for at least a portion of a subsequent optimization period, as a function of said achievement output corresponding thereto, such that the or each of said adjusted rate response functions defines an increased or decreased change in desired pacing rate corresponding to said predetermined change in sensor output for the or each of said sensing means; and

4) output means for providing an optimized pacing rate of stimulation pulses as a function of the or each of said derived desired pacing rates."

The wording of claim 2 reads as follows:

"2. A rate responsive cardiac pacemaker (100) for providing an optimized pacing rate of stimulation pulses as a function of at least two selected rate

control parameters, each of said rate control parameters having a value which varies as a function of changes in a patient's physiological demand, comprising:

A) two or more sensor means (S_1, S_2) for sensing each of said rate control parameter values and for providing a sensor output representative thereof;

B) control means (114) coupled to each of said sensor means, comprising:

(1) rate response defining means for deriving a desired pacing rate for each of said sensor outputs, thereby defining a predetermined rate response function for each of said sensor outputs which correlates each sensor output with a correspondingly desired pacing rate, such that for a predetermined change in sensor output a corresponding change in desired pacing rate is provided;

(2) achievement monitoring means having a predetermined achievement criterion for each of said sensor outputs which is reflective of desired pacing rates to be achieved for expected levels of exercise of said patient over a predetermined optimization period, said achievement criterion comprising, for each of said sensor outputs, a pacing rate component and a duration component, the pacing rate component being a preselected rate and the duration component being a minimum time interval over which the desired pacing rate must exceed the preselected rate, said achievement monitoring means monitoring the number of times each of said derived desired pacing rates exceeds said rate component for more than said duration component, within said optimisation period, and for providing an

achievement output indicative of this number;

3) rate response control means for adjusting each of said rate response functions, for at least a portion of said *[Note of the Board: it should read "a"]* subsequent optimization period, as a function of said achievement output corresponding thereto, such that each of said adjusted rate response functions provides an increased or decreased change in desired pacing rate corresponding to said predetermined change in sensor output for each of said sensor means; and

(4) sensor weighting control means for adjusting an adjustable sensor weighting value, for at least a portion of a *[Note of the Board: it should read "said"]* subsequent optimization period, as a function of each of said achievement outputs

(5) output means for providing an optimized pacing rate of stimulation pulses derived from each of said adjustable sensor weighting values and each of said derived desired pacing rates, said sensor weighting value weighting the relative contribution which each of said derived pacing rates contributes toward determining said optimized pacing rate."

Claim 3 is dependent on claim 2.

VIII. The arguments of the appellant can be summarised as follows:

The present invention provided a self-adaptive rate responsive cardiac pacemaker comprising one or more sensors and means for deriving a desired pacing rate as a function of a sensor's output. An achievement

monitoring means monitored the relationship between the desired pacing rate associated with a sensor's output and a corresponding achievement criterion, and provided an achievement output indicative of the pacemaker's ability to meet the patient's physiological needs. The rate response function of a sensor was then adjusted as a function of the corresponding achievement output in order to increase or decrease the sensor's gain if the sensor was underachieving or overachieving. Hence, the control provided by the present invention was not merely a calibration procedure as disclosed in document D2. Furthermore, none of the cited prior art documents suggested to monitor the output of a sensor by means of an achievement criterion comprising a rate component and a duration component as specified in claims 1 and 2 in order to adjust the sensor's gain to the patient's ongoing metabolic needs. Therefore, the subject-matter of these claims involved an inventive step within the meaning of Article 56 EPC.

Reasons for the Decision

1. The appeal is admissible.

Amendments

2.1 Claim 1 comprises the subject-matter of claim 1 according to the patent as maintained by the opposition division and differs from this claim essentially in that the **achievement criterion** of the achievement monitoring means is defined as comprising:

(a) "a pacing rate component and a duration component,

the pacing rate component being a preselected rate and the duration component being a minimum time interval over which the desired pacing rate must exceed the preselected rate";

and in that the **achievement monitoring means** monitors:

(b) "the number of times the or each of said derived desired pacing rates exceeds said rate component for more than said duration component within said optimisation period, and for providing an achievement output indicative of this number".

2.2 Features (a) and (b) find support in the application as published (cf. page 10, line 31 to page 11, line 16) and restrict the scope of protection defined by claim 1 as granted.

2.3 Claim 2 comprises the features of claims 2 and 3 considered in the contested decision and the above features (a) and (b).

2.4 The Board has no reason to doubt that the subject-matter of the claims according to the patent as maintained by the opposition division is disclosed in the application as originally filed.

The further amendments made to the description and to Figure 5 do not add new subject-matter.

2.5 Hence, the Board is satisfied that the documents according to the appellant's request are admissible under Articles 123 (2) and (3) EPC.

Inventive step

3.1 The patent in suit relates to a self-adaptive, rate responsive cardiac pacemaker comprising one or more physiological sensors and is essentially concerned with the automatic adjustment of the **rate response function** converting a sensor's output into a corresponding **desired pacing rate** (cf. claim 1). According to a further embodiment of the invention (cf. claim 2), the automatic adjustment involves also the **weighting value** attributed to each desired pacing rate when the **optimized pacing rate** is determined.

3.2 According to an essential aspect of the invention, these adjustments are performed by comparing the pacing rates derived from a sensor's output ("**desired pacing rates**") with a corresponding **achievement criterion** which reflects the expected level of physical exertion experienced by a patient over a predetermined **optimization period.**

4.1 Document D2, which represents the closest prior art, shows a rate responsive cardiac pacemaker for providing an optimised pacing rate of stimulation pulses as a function of rate control parameters which are, *inter alia*, related to the patient's metabolic needs. The relationship between exertion and cardiac output is defined by means of a first table stored in a memory. In a calibration phase, a conversion table correlating measured physiological parameters and exertion data for a particular patient is generated and added to the pacemaker's memory. After the elapse of the calibration phase, the appropriate pacing rate is determined as a function of a physiological sensor's output by combining the data of the first table with the data of the conversion table. Hence, in operation, the

pacemaker determines the pacing rate as a function of the measured physiological parameter.

4.2 As shown in Figure 5, the pacemaker of D2 comprises "evaluators" which convert each sensor's output into a variable comparable to the "desired pacing rate" of the present invention. As pointed out in D2 (column 18, line 68, to column 19, line 11), the transfer characteristics of the evaluators are programmable. The evaluators' outputs are combined into a "calculated required rate" corresponding to the "optimized pacing rate" of the present invention, whereby the contribution of each sensor to the "calculated required rate" is a function of the corresponding programmable weighting factor.

4.3 D2 teaches that the choice of an evaluator's transfer function depends on the fulfilment of certain criteria, such as the attainment of certain operating values. According to a particular embodiment (cf. D2, column 15, lines 7 to 29), the operating behaviour of the pacemaker can be modified automatically by taking into account the occurrence of certain events or the frequency with which predetermined operating values are adhered to. For instance, if blood temperature is the physiological parameter used to monitor physical exertion, it is assumed that an increase in blood temperature is related to an increase in physical exertion only when it is limited in time. If a predetermined blood temperature increase exceeds a predetermined time duration, the functional relationship between blood temperature and physical exertion is modified in order to avoid a fever condition resulting in a permanent increase in the pacing rate (cf. D2, column 16, lines 13 to 22).

5.1 The subject-matter of claim 1 of the patent in suit differs from the pacemaker known from D2 essentially in that the pacemaker adjusts the rate response function linking a measured physiological parameter to a desired pacing rate (ie a sensor's gain) as a function of an achievement criterion reflecting the expected physiological demands of the patient over a predetermined optimization period. In other words, the pacemaker of claim 1 monitors the number of times a desired pacing rate obtained from a sensor's response to a physiological parameter exceeds a predetermined value for a predetermined time interval and, based on this monitoring, adjusts the sensor's response (ie its gain). Thus, each sensor's rate response is automatically optimised during the normal operation of the pacemaker depending on the ability of the sensor's gain to achieve a pacing rate which meets the patient's expected metabolic needs.

5.2 Though it is known to calibrate a sensor's gain by comparing the sensor's actual response with an expected value for a predetermined degree of exertion, neither D2 nor any of the documents cited in the course of the opposition proceedings hints at the possibility of continuously **monitoring** and **adjusting** a sensor's rate response on the basis of the achievement criterion specified in claim 1.

6. For these reasons, the Board finds that, in the light of the known prior art, it was not obvious to a skilled person starting from D2 to arrive at a pacemaker falling within the terms of claim 1. Hence, the subject-matter of this claim involves an inventive step within the meaning of Article 56 EPC.

7. Claim 2 relates to a pacemaker with two or more sensors and comprises additional features relating to the adjustment of weighting values. For the same reasons given above, the subject-matter of this claim also complies with the requirements of Article 56 EPC.

Claim 3 is dependent on claim 2, and, thus, its subject-matter involves an inventive step.

8. In summary, the Board finds that the appellant's request is allowable and that the patent can be maintained on the basis thereof.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of the first instance with the order to maintain the patent on the basis of the appellant's request (cf. point VI).

The Registrar: The Chairman:

R. Schumacher G. Davies