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D E C I S I O N
of 3 December 2002

Case Number: T 0739/98 - 3.4.1

Application Number: 85905293.8

Publication Number: 0220194

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:

Stimulated heart interval measurement, adaptive pacemaker and method of operation

Patentee:

St. Jude Medical AB

Opponent:

Biotronik Mess- und Therapiegeräte GmbH & Co
Ingenieurbüro Berlin

Headword:

-

Relevant legal provisions:

EPC Art. 54, 56

Keyword:

"Main request - Novelty and Inventive step (yes)"

Decisions cited:

-

Catchword:

-



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Boards of Appeal

Chambres de recours

Case Number: T 0739/98 - 3.4.1

**D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 3 December 2002**

(Opponent)

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Respondent:

(Proprietor of the patent)

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Representative:

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted 20 May 1998
rejecting the opposition filed against European
patent No. 0 220 194 pursuant to Article 102(2)
EPC.**

Composition of the Board:

Chairman: G. Davies

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

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal, received on 21 July 1998, against the decision of the opposition division, despatched on 20 May 1998, rejecting the opposition against the European patent No. 0 220 194. The appeal fee was paid on 21 July 1998 and the statement setting out the grounds of appeal was received on 12 September 1998.
- II. The opposition had been filed against the patent as a whole, based on Article 100(a) EPC and concerned, in particular, objections under Articles 52(1), 54 and 56 EPC.
- III. In the statement of grounds of appeal, the appellant referred to the following documents:
- D1: EP-A-0 007 189
- D3: US-A-4 313 442
- D4: US-A-4 305 396
- D6: US-A-4 284 082
- IV. In response to a communication from the Board summoning the parties to oral proceedings, the respondent (patentee) filed three auxiliary requests by letter dated 30 October 2002, received on 31 October 2002.
- V. Oral proceedings were held on 3 December 2002.
- VI. The appellant requested that the decision under appeal be set aside and the patent revoked.

The respondent requested that the appeal be dismissed (**main request**), or that the patent be maintained on the basis of the following documents:

first auxiliary request: Claims: 1 filed on 31 October 2002,
2 to 7 as granted,
Description and Figures as granted;

second auxiliary request: Claims: 1 filed on 31 October 2002,
2 to 7 as granted,
Description and Figures as granted;

third auxiliary request: Claims: 1 filed on 31 October 2002,
2 to 5 as granted,

Description: amended pages 3, 4, 6, 8, 10, 12-15, 17, 24 and 26 filed on 31 October 2002;
remaining pages as granted;

Figures: amended Figures 13A and 15A to D filed on 31 October 2002;
remaining Figures as granted.

VII. The wording of claim 1 as granted reads as follows:

"A rate adaptive pacemaker (16) having means (42, 44; 22, 24; 30, 36) for generating and delivering

*stimulation pulses on demand and at a programmable rate, physiological response means (71, 73) for adjusting said rate as a function of an interval between the generation of a stimulation pulse and the occurrence of a responsive cardiac event, **characterised in that** said physiological responsive means (71, 73) comprises:*

sensing means (48, 54, 56) for sensing the occurrence of a cardiac depolarization event, referred to as X, which depolarization event follows the delivery of a stimulation pulse, referred to as S, to a heart (18); timing means (71) for measuring the S - X time interval between the generation of said stimulation pulse S and the occurrence of said sensed cardiac depolarization event X;

means (73) for automatically adjusting the rate at which the stimulation pulses are delivered to the heart as a function of said S - X time interval measured by said timing means (71)."

Claims 2 to 7 are dependent on claim 1.

VIII. The appellant argued essentially as follows:

Document D6 related to a pacemaker comprising **timing means** for defining a predetermined time window, **sensing means** for detecting the occurrence of ventricular depolarization events within the predetermined time window and **means for automatically adjusting** the pacing rate as a function of the sensed cardiac depolarization events. Since the detection of a ventricular depolarization event within a predetermined time window defined with respect to a stimulation pulse identified the time interval S - X between the generation of a

stimulation pulse S and the occurrence of a sensed cardiac depolarization event X, the timing means shown in D6 corresponded in effect to the timing means recited in claim 1 of the contested patent. Since D6 disclosed all the features of claim 1, the subject-matter of this claim was not new within the meaning of Article 54 EPC.

Even it were assumed that claim 1 of the patent in suit was novel over D6 because the latter did not disclose the same kind of timing means, the claimed subject-matter would not be inventive.

D6 dealt with the question of achieving synchronism between the atrium and the ventricle when, as a result of increased physiological demand, the ventricle started beating at a rate higher than the atrial pacing rate. Starting from this document, the problem addressed by the patent in suit consisted in developing a demand pacemaker which adjusted the rate on the basis of a parameter responsive to changes in the patient's physiological demand. D6 taught that an increasing load applied to the patient's heart affected the ventricular rate and that the resulting shortening of the time interval A - V between an atrial stimulation pulse A and the following ventricular depolarization V could be used to control the rate at which the atrium was paced. In the light of such teaching, it would have been obvious to a person skilled in the art to use the time interval A - V to control the pacing rate in a rate adaptive pacemaker. As a result, the skilled person would have arrived at a pacemaker falling within the terms of claim 1 of the patent in suit.

Furthermore, it was known from D1 to use the time interval between a stimulation pulse and a cardiac

repolarization event as rate control parameter in a rate adaptive pacemaker. Though D1 mentioned explicitly only the time interval between a stimulation pulse and the following T-wave, it did not exclude the possibility that other time intervals could be derived from the heart's electrical response to a stimulation pulse. This disclosure coupled with the teaching of D6, that the time interval between atrial stimulation and ventricular depolarization was affected by the patient's physiological condition, would have directed the skilled person to the claimed invention. Hence, also in the light of D1 and D6, the subject-matter of claim 1 did not involve an inventive step within the meaning of Article 56 EPC.

IX. The respondent's arguments can be summarized as follows:

Document D6 sought to provide a solution to the problem caused by the ventricular rate becoming disassociated from the rate of the paced atrium. The teaching of D6 consisted essentially in increasing the pacing rate of the atrium when a depolarization of the ventricle was detected outside a predetermined time window. Consequently, the timing means referred to in D6 were in effect time window generating means and, as such, unsuitable for measuring time intervals as required by the rate control of the present invention. Hence, document D6 did not take away the novelty of the subject-matter of claim 1.

Furthermore, D6 did not relate to a rate adaptive pacemaker and thus could not provide a suitable starting point for the claimed invention. As to D1, this document taught to control the pacing rate as a

function of the time interval between a stimulation pulse and the following T-wave, and it did not provide any incentive to look for different time intervals. Hence, neither D6 nor D1 could have led the skilled person to the claimed rate adaptive pacemaker.

Reasons for the Decision

1. The appeal is admissible
- 2.1 The contested patent relates essentially to a rate adaptive pacemaker which utilises the time interval S - X between the application of a stimulation pulse S to the atrium or ventricle and the resulting atrial or ventricular depolarization X as parameter indicative of the patient's metabolic demands.
- 2.2 According to a **first embodiment**, the time interval S - X is the **A-P interval**, ie the time interval between an atrial stimulation pulse, or A-pulse, and the corresponding P-wave indicative of atrial depolarization. In a **second embodiment**, available for use when AV conduction of the heart is not blocked, the time interval is the **A-R interval**, ie the time interval between an A-pulse and the following R-wave generated by a ventricular depolarization. In a **third embodiment**, the time interval is the **V-R interval**, ie the time interval between a ventricular stimulation pulse (V-pulse) and the corresponding ventricular depolarization (R-Wave) (see patent specification, page 3, lines 8 to 25).

Respondent's main request

Novelty

- 3.1 According to the appellant, the pacemaker shown in document D6 comprises all the features recited in claim 1 of the contested patent and, in particular, "timing means" for measuring the S - X time interval between a stimulation pulse S and the following cardiac depolarization event. The appellant's argument rests essentially on the assumption that in D6 the determination of the occurrence of a ventricular depolarization within a predetermined (narrow) time window defined with respect to the preceding atrial stimulation pulse is equivalent to the measurement of the time interval between the application of said pulse and the following ventricular depolarization.
- 3.2 Document D6 relates to a ventricular synchronised atrial pacemaker and deals, in particular, with the problem of stimulating the atrium at a rate which maintains atrial-ventricular synchrony in response to ventricular electrical activity or depolarization not accompanied by a **naturally** occurring preceding atrial electrical activity or depolarization (see column 3, lines 30 to 38). If a ventricular depolarization event (*ie* an R-wave) occurs within **a time window** defined with respect to an atrial stimulation pulse (A-pulse) **or** prior to the delivery of an atrial stimulation pulse, the rate of atrial stimulation is increased. In other words, the pacer according to D6 increases the pacing rate when the time interval A - V between an A-wave and the following R-wave lies **outside** a predetermined expected range corresponding to a "blanking" time window and delimited by two "sensing" time windows.
- 3.3 The Board agrees with the appellant that, in principle,

time windows can be used to measure time intervals. In fact, the wording of claim 1 does not exclude "timing means" which may effect a measurement of the S - X time interval by defining a plurality of predetermined (narrow) time windows and by detecting in which time window a cardiac depolarization event occurs. However, there can be no doubt, in the opinion of the Board, that the time windows used in the pacemaker of D6 are not the "timing means" of claim 1 in the sense that they are not suitable for determining the **actual length** of an A - V interval since such parameter is irrelevant for the teaching of D6.

Thus, an essential difference between the claimed invention and the pacemaker of D6 is that in the former the "timing means" is actually required to **measure** a time interval between stimulation and depolarization, while in the latter the "timing means" simply provides a time window for "blanking" expected depolarization events and two neighbouring time windows for sensing depolarization events disassociated from the paced atrium. In other words, the timing means of D6 allows only to discriminate between ventricular contractions which are "in time" and those "out of time", whereas the claimed invention requires timing means which can provide a measurement of the time interval separating a depolarization from the preceding stimulation.

- 3.4 Since D6 does not disclose a pacemaker comprising timing means as specified in claim 1 of the patent in suit, the subject-matter of this claim is new within the meaning of Article 54 EPC.

Inventive step

- 4.1 In its submissions relating to the alleged lack of inventive step of the claimed invention, the appellant relied essentially on D6 and on a combination of the teachings of D1 and D6. In particular, the appellant argued that D6 showed a clear correlation between an increased ventricular rate and the patient's physiological need, and that, on the basis of this teaching, it would have been obvious to a person skilled in the art to arrive at the rate adaptive pacemaker recited in claim 1 of the contested patent.
- 4.2. It is specified in D6 (column 2, lines 42 to 51, emphasis added) that "if a patient has an absolute sinus bradycardia (that is, is devoid of an underlying atrial heart rhythm), then if an increasing load is applied to the patient's heart, the heart rate of the ventricle may increase to a rate exceeding the preset rate of the atrial pulse generator timing thereby inhibiting atrial stimulation. The atrium no longer pumps in synchrony with the ventricle and the patient loses the atrial contribution to cardiac output. Thus, in a time of need, the patient may suffer cardiac insufficiency".
- It could therefore be argued that also in D6 the timing of ventricular depolarization after the stimulation of the atrium, ie the A-R interval referred to in the contested patent, is considered to reflect the patient's metabolic demand, at least for some heart conditions.
- 4.3 However, there is no indication in D6 that such time interval may be used as rate control parameter for setting the pacing rate. In fact, the pacemaker of D6 teaches to react to the occurrence of an underlying ventricular heart rhythm, which is disassociated from

the paced atrium and capable of increasing with the patient's physiological requirements, by increasing the atrial pacing rate in steps until synchronism between atrial and ventricular depolarizations is reestablished. In the absence of any R-wave outside the expected time window, the pacemaker subsequently lowers the pacing rate in steps to a predetermined minimum rate. Hence, D6 merely teaches to increase the atrial pacing rate in response to changes in the ventricular rate and to decrease it according to a preprogrammed pattern. In other words, the pacemaker of D6 responds to changes in the patient's physiological conditions only in the sense of stepping up the pacing rate, whereas a rate adaptive pacemaker presupposes a **reversible** control of the pacing rate in response to changes in the value of a physiological control parameter.

- 4.4 Hence, in the Board's opinion, the teaching of document D6 gives the skilled person no hint to develop a rate adaptive pacemaker falling within the terms of claim 1 of the patent in suit.

- 4.5 Document D1 relates to a rate responsive pacemaker in which the rate is controlled as a function of the time interval between a stimulation pulse and the corresponding T-wave. As pointed out in D1 (see page 2, line 26 to page 3, line 9), this use of the S - T interval (*ie* of the interval between stimulation and ventricular **repolarization**) is based on the "realisation that the period of ventricular repolarisation - the interval between the onset of ventricular depolarisation (the QRS complex) and repolarisation (the T Wave) - decreases with increase in heart rate, due to the action of hormones released

into the blood stream with cardiac effects".

As there is no indication in D1 that other time intervals, such as a time interval S - X between the application of a stimulation pulse S and a cardiac **depolarization** event X, might correlate with the patient's physiological need, it is not plausible to assume that D1 would incite the skilled person to look for a viable alternative to the S - T interval as rate control parameter.

- 4.6 As to a possible combination of D1 and D6, it is merely pointed out in D6 (see column 2, lines 42 to 48) that, in case of an absolute sinus bradycardia, an increasing load applied to the patient's heart **may** increase the heart rate of the ventricle above the **preset** atrial rate and thus inhibit atrial stimulation. In the opinion of the Board, the teaching to increase the atrial pacing rate in response to the detection of an abnormal depolarization event cannot be interpreted as a suggestion that there is a reliable correlation between the patient's physiological demand and the length of the A - V interval.
- Hence, the skilled person had no reason to assume that the teaching of D6 concerning the control of the atrial stimulation rate could be applied to a rate adaptive pacemaker.

- 5.1 In the course of the written procedure, the appellant referred also to documents D3 and D4.
- 5.2 D3 relates to a rate responsive pacemaker and teaches, *inter alia*, to control the pacing rate "as a function of detected changes of the P-wave rate" (column 2, lines 5 and 6). As pointed out in D3 (column 4,

lines 38 to 43), in "patients suffering from second or third degree heart block there is no longer a one-to-one relationship between atrial contractions and ventricular contractions. The atria will continue to contract at the rate established by the nerve impulses, but the ventricles may adopt a slower rate." Since "even in patients suffering from second or third degree heart block and even in instances where atrial fibrillation is in progress, changes in the body's metabolic need still reflect changes in the atrial electrical activity" (see column 4, lines 56 to 60), D3 suggests using changes in the **average rate of detected P-waves** to produce a corresponding rate in the ventricular rate (see column 3, lines 11 to 16). Hence, D3 discloses a rate control which is suitable for a patient with normal atrial activity or, at least, with an atrial activity which is responsive to the patient's metabolic need, and, in fact, there is no suggestion in D3 that cardiac demand might be related to the time interval between atrial stimulation pulses and P-waves following such pulses.

- 5.3 According to D4, there is a correlation between the optimum heart rate and the time interval between a stimulation pulse and the corresponding "T-wave", since this time interval carries information relating to the patient's physiological condition (see column 1, lines 17 to 25). Furthermore, D4 (see column 1, lines 33 to 64) teaches that the optimum heart rate correlates also with the frequency spectrum and the amplitude of the QRS complex or the T-wave. Consequently, D4 proposes a pacemaker comprising means for detecting the T-wave and the QRS complex (both spontaneous and evoked) within corresponding time windows (see figure) and means for detecting different

components of the QRS complex or T-wave. These components may be the frequency composition, the amplitude and "the time period, or length of the T wave, such as between the time when it has risen to a predetermined voltage level and the time when it has fallen back to the same voltage level" (see column 5, lines 51 to 56).

6.1 In summary, the following conclusions relating to the skilled person's knowledge before the priority date of the contested patent can be drawn from the cited prior art:

- the electrical activity of the heart responds to the patient's physiological conditions, in particular, to changes in physiological demand;
- suitable rate control parameters for a rate adaptive pacemaker are the S - T time interval (see D1 and D4), components of the QRS complex or of the T-wave (D4) and the average rate of detected P-waves;
- the timing of the R-waves with respect to the atrial stimulation pulses can be used to maintain synchronism between atrial and ventricular depolarizations (D6).

6.2 It may be argued that the above disclosures show a clear interest in obtaining rate control parameters based on the electrical activity of the heart, and that it would have been obvious to the skilled person to investigate further and thus arrive at the claimed invention. However, in the opinion of the Board, there is no indication in the cited prior art that the time

interval between the delivery of a stimulation pulse and the occurrence of a cardiac **depolarization** event following such stimulation pulse behaves as a function of physiological demands.

- 6.3 In the result, the Board finds that, in the light of the cited prior art, it would not have been obvious to a person skilled in the art, starting from the teaching of D6 or from the rate adaptive pacemaker shown in D1, to arrive at a pacemaker falling within the terms of claim 1 of the contested patent. Hence, the subject-matter of this claim involves an inventive step within the meaning of Article 56 EPC.
7. In conclusion, the grounds for opposition do not prejudice the maintenance of the patent as granted and, consequently, there is no need to consider the respondent's auxiliary requests.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

The Registrar:

The Chairman:

R. Schumacher

G. Davies

