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**D E C I S I O N**  
**of 25 July 2002**

**Case Number:** T 0704/98 - 3.4.1

**Application Number:** 88311643.6

**Publication Number:** 0325851

**IPC:** A61N 1/365

**Language of the proceedings:** EN

**Title of invention:**

Rate-responsive, distributed-rate pacemaker

**Patentee:**

TELECTRONICS N.V.

**Opponent:**

BIOTRONIK Mess- und Therapiegeräte GmbH & Co Ingenieurbüro  
Berlin

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 123(3), 56

**Keyword:**

"Extension of protection (yes; main request)"

"Inventive step (yes; first auxiliary request)"

**Decisions cited:**

-

**Catchword:**

-



**Case Number:** T 0704/98 - 3.4.1

**D E C I S I O N**  
**of the Technical Board of Appeal 3.4.1**  
**of 25 July 2002**

**Appellant:** BIOTRONIK  
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**Representative:** Eisenführ, Speiser & Partner  
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**Respondent:** TELELECTRONICS N.V.  
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**Representative:** Hackett, Sean James  
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**Decision under appeal:** Interlocutory decision of the Opposition Division  
of the European Patent Office posted 5 May 1998  
concerning maintenance of European patent  
No. 0 325 851 in amended form.

**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 14 July 1998, against the decision of the opposition division, dispatched on 5 May 1998, maintaining European patent No. 0 325 851 in amended form. The appeal fee was paid on 14 July 1998 and the statement setting out the grounds of appeal was received on 4 September 1998.

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

III. Of all the documents cited during the opposition and the appeal, only the following remain relevant to the present decision:

D1: J.G. Truxal: "Entwurf automatischer Regelsysteme",  
R. Oldenburg, Wien und München (1960), pages 435  
to 480;

D3: EP-A-0 225 839

D4: US-A-4 513 743

D6: US-A-4 399 820

IV. Oral proceedings were held on 25 July 2002.

V. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patentee) requested that the patent be maintained on the basis of the following documents:

**Main request:**

Claim 1 filed in the oral proceedings of 25 July 2002;

Columns 1 and 2 of the description filed in the oral proceedings and columns 3 to 12 of the description as maintained by the opposition division;

Figures: sheets 1/4 to 4/4 of the patent as granted.

**First auxiliary request**

Claim 1 filed in the oral proceedings with description and Figures as for the main request.

**Second auxiliary request**

Claim 1 filed in the oral proceedings with description and Figures as for the main request.

**Third auxiliary request**

Claim 1 filed in the oral proceedings with description and Figures as for the main request.

VI. The wording of claim 1 of the **main request** reads as follows:

"1. A rate-responsive heart pacer comprising means for measuring the value of the rate-control parameter (RCP);

means (25) for generating pacing pulses at a rate; means for adjusting the rate; and control means (15):

(a) for calculating the total percentage of time, over an interval of at least one day which is greater than the response time of the control means by an amount sufficient for the control means to adapt to long term changes in said RCP, that said RCP value is

equal to or less than each of at least several values,

(b) for representing a desired rate distribution, said representation including, for each of different percentages of time, a set rate equal to or greater than that which is desired, and

(c) responsive to a measured value of said RCP, for relating the calculated total percentage of time for that RCP to said represented desired rate distribution to derive said set rate corresponding to said calculated total percentage of time and causing said adjusting means to adjust the rate at which said pulse generating means operates to said set rate"

The wording of claim 1 according to the **first auxiliary request** reads as follows:

"1. A rate-responsive heart pacer comprising a control system, the control system comprising means for measuring the value of a controlling parameter; means for adjusting a controlled parameter; and control means (15) (a) for calculating the total percentage of time, over an interval of at least one day which is greater than the response time of the control system by an amount sufficient for the control system to adapt to long term changes in the controlling parameter, that said controlling parameter is equal to or less than each of at least several values; (b) for representing a desired controlled-parameter distribution which for each of different percentages of time indicates a controlled parameter equal to or greater than that which should characterize the system operation; and (c) for responding to a measured value of said controlling parameter, for relating the calculated total percentage of time for that controlling parameter to the desired controlled parameter for that percentage of time and

for causing said adjusting means to adjust said controlled parameter to equal said desired controlled parameter, wherein the controlling parameter is a rate-control parameter (RPC), and means (25) is provided for generating pacing pulses which can be set to operate to said desired rate."

Claim 1 according to the **second auxiliary request** differs from claim 1 of the main request in that in feature (b) the desired rate distribution is specified "as a cumulative distribution function".

Claim 1 according to the **third auxiliary request** differs from claim 1 of the first auxiliary request in that in feature (b) the desired controlled-parameter distribution is specified "as a cumulative rate distribution".

VII. The appellant argued essentially as follows:

**Main request**

Claim 10 of the patent as granted concerned a rate-responsive heart pacemaker comprising a control system according to claim 9. Feature (c) of claim 9 specified that the calculated total percentage of time for the measured value of the controlling parameter was related to the desired controlled parameter for the same percentage of time. In claim 1 according to the main request, the calculated total percentage of time for a measured value of the rate-control parameter (RCP) was related to the "represented desired rate distribution" to derive a set rate corresponding to the calculated total percentage of time. Hence, claim 1 of the main request referred to a "set rate" which did not necessarily coincide with the desired rate for the

total percentage of time associated with a measured value of RCP. Since claim 1 according to the main request related to embodiments which were not covered by the granted claims, it extended the scope of protection and, thus, was not admissible under Article 123(3) EPC.

**First auxiliary request**

The only features of claim 1 according to the first auxiliary request which were not explicitly disclosed in document D3 were features (a), (b) and (c) of the control means. D3, however, taught to count the number of occurrences of certain events and to compare such counts with some predetermined values in order to control the functioning of the pacemaker. The counting of the occurrences of an event detected by measuring some physiological parameter was essentially equivalent to generating a distribution function for the values of such parameter. Since the response of the pacemaker eventually affected the pacing rate distribution, D3 implicitly taught to control the pacing rate by linking the distribution function of a physiological parameter to a desired pacing rate distribution.

However, even if the novelty of claim 1 over D3 were to be acknowledged, its subject-matter could not be regarded as inventive, because it would have been obvious to a person skilled in the art, starting from the teaching of D3, to arrive at a rate-responsive pacer in which the pacing rate was controlled as a result of the claimed comparison between distribution functions.

Furthermore, the teaching of the contested patent consisted essentially in generating an histogram of

measured RCP values and in correlating said histogram with the histogram of desired pacing rates. It was obvious to a person skilled in the art to apply a principle generally known in the field of automatic control systems (see D1) to a pacemaker known from document D3 or D6. This view was also supported by the fact that the use of histograms of measured parameters was known in the field of pacemaker's (see D4).

Hence, the subject-matter of claim 1 according to the first auxiliary request was not new with respect to the teaching of D3 (Article 54 EPC) or, at least, it did not involve an inventive step within the meaning of Article 56 EPC.

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

**Main request**

The wording of claim 1 took account of the fact that the distribution functions were quantised and that the calculated percentage of time for a measured rate-control parameter did not always represent a value of the quantised desired rate distribution, so that the next higher value was selected as set rate. Though the wording of claim 1 according to the main request and, in particular, feature (c), differed from the claim as granted, this merely served the purpose of better specifying the present invention and did not extend the protection conferred by the patent as granted. Hence, claim 1 of the main request was admissible under Article 123(3) EPC.

**First auxiliary request**

Document D3 was essentially concerned with the problem



of linking together different physiological parameters so that they could be used to control a pacemaker. It did not address the problem of determining the pacing rate as a function of the distribution function of a rate-control parameter. Though D3 taught in general terms to count the number of events and generate a distribution function for this event, it did not specify or even suggest that such distribution function could be linked to a distribution function representative of desired pacing rates. Hence, the subject-matter of claim 1 of the first auxiliary request was new and involved an inventive step.

### Reasons for the Decision

1. The appeal is admissible.
  
- 2.1 The contested patent is concerned with a rate-responsive pacemaker having a **predetermined rate distribution independent** of the **distribution of the rate-control parameter** (see patent specification, column 1, first paragraph). As pointed out in the description (ibid. column 1, lines 18 to 20), a rate-responsive pacemaker generally exhibits some characteristic which expresses the desired rate as a function of a rate-control parameter (RCP). However, pacemakers having a predetermined functional relationship between desired pacing rate and RCP require complex set up procedures to account for variations in the values of the RCP for any given state of stress or exercise during the life of the pacemaker (see ibid. column 1, lines 24 to 36).
  
- 2.2 The pacemaker of the present invention is not

programmed to pace at a particular rate for a particular value of the rate control parameter. Instead, the control of the pacing rate is based on a **distribution function of desired pacing rates**, which is stored in the pacemaker, and on a **distribution function of recent RCP values**, which is generated and periodically updated by the pacemaker. According to a preferred embodiment, two percentile rankings are developed from these two functions, whereby each percentile ranking represents a cumulative distribution function of desired pacing rates or of previous RCP values (see Figures 4A, 4B and 5A, 5B).

The pacing rate desired to cope with a particular state of stress or of physical exercise is determined at any instant on the basis of such cumulative distribution functions and of the percentile ranking associated with the measured RCP value, as shown in Figures 4B, 5B and 6 of the contested patent. The result is that the rates at which the pacemaker paces the patient's heart have a probability distribution which corresponds to the desired (programmed) rate distribution.

- 2.3 In other words, the contested patent seeks to control the pacing rate of a rate-controlled pacemaker on the basis of a probability distribution function of RCP values measured over a certain time period and of a programmed probability distribution function of desired pacing rates, so that the pacing rate exhibits a predetermined distribution regardless of the distribution of the measured RCP values.

*Main request*

- 3.1 Independent claim 10 of the patent as granted relates

to a "rate-responsive heart pacer comprising a control system according to claim 9", whereby such control system comprises, *inter alia*,

- control means "(c) for responding to a measured value of said controlling parameter, for relating the calculated total percentage of time for that controlling parameter to the desired controlled parameter for that percentage of time".

3.2 The corresponding feature (c) recited in claim 1 of the main request reads as follows:

- control means "(c) responsive to a measured value of said RCP, for relating the calculated total percentage of time for that RCP to said represented desired rate distribution to derive said set rate corresponding to said calculated total percentage of time "

3.3 As pointed out by the appellant, features (c) of claim 9 implies that there is a direct link between the controlling parameter and the desired controlled parameter for a given percentage of time, whereas claim 1 according to the main request does not specify such direct correspondence. In fact, the "set rate" associated with a certain calculated total percentage of time need not be the desired rate for that percentage of time. In particular, if the quantisation of the probability distributions does not provide an exact correspondence between the time percentages for a measured control parameter and for the desired pacing rate, the desired rate associated with the next higher time percentage becomes the derived "set rate" (see Figure 6 of the patent specification).

- 3.4 For the above reasons, the Board finds that claim 1 according to the main request extends the scope of protection conferred by the granted patent and therefore is not admissible under Article 123(3) EPC.

*First auxiliary request*

4. Claim 1 according to the first auxiliary request is admissible under Articles 123(2) and (3) EPC since it corresponds essentially to claim 10 of the patent as granted.
- 5.1 In the oral proceedings, the appellant acknowledged that D3 did not explicitly show control means comprising features (a), (b) and (c) as specified in claim 1 of the first auxiliary request but argued that the teaching of D3 implicitly disclosed or at least suggested this combination of features. In particular, the appellant pointed out that the pacemaker shown in D3 counted certain events relating to a physiological parameter and that, by counting these events, it generated a probability distribution of parameter values which was then correlated with some preset values in order to act on the response of the pacemaker. In other words, D3 taught to modify the response of the pacemaker, and ultimately its pacing rate, as a result of the comparison between a measured probability distribution and preset values which represented a programmed probability distribution.
- 5.2 On the other hand, the respondent argued that the teaching of D3 did not go beyond the mere fact of using the distribution function of some events monitored over a time interval to modify the behaviour of the pacemaker and, thus, it did not imply the direct

correlation between the probability distributions of RCP values and desired rates specified in claim 1.

5.3 The teaching of D3 concerning the functional relationships used to control a pacemaker may be summarized as follows (see D3 page 34, line 16 to page 35, line 11):

- pure control functions are formed by simple linkage of input measured variables of address variables and by the pacing parameters as stored values;
  
- regulation functions are realized in a corresponding manner, with measured input variables being converted by corresponding characteristic fields into a variable that is representative for the physical exertion, in accordance with the required cardiac output. This variable addresses the characteristic field together with a variable representative of the current stroke volume, and the then necessary heart rate can be read out of the individual memory locations;
  
- the calibration of a measured variable dependent in particular on exertion is effected by providing that, in the calibration period, the value expected (and optionally ascertained by a different measuring method) is respectively written into the memory location addressed by the current measured variable. In particular, to this end the exertion ascertained externally by means of an ergometer is written into a memory to be addressed by means of the measured variable or

variables characterising the exertion, in each case in form of a value. This value in turn, during the subsequent operating state, addresses the corresponding rate in a characteristic field, and this rate is selected such that (in particular in the case of combined addressing with a measured value representative of the current stroke volume) the product of the stroke volume and the rate, as the cardiac output, corresponds to and is followed up with the ascertained current exertion variable.

5.4 Hence, the Board agrees with the respondent that D3 does not teach to establish a functional relationship between rate control parameter values and pacing rates by means of their respective probability distributions. The monitoring and counting of events referred to by the appellant, relate to the possibility of varying the pacer's operating behaviour in a self-teaching manner in accordance with a certain frequency of events such as, for instance, faults of a predetermined frequency or intensity (see D3, page 31, line 7 to 27), whereby the change in operating behaviour is effected by switching between different programmed characteristic fields or by changing their weighting or linkage (see D3, page 31, lines 10 to 15). Furthermore, there is no suggestion in D3 that a distribution function obtained by monitoring past values of the rate control parameter could be directly linked to a programmed distribution function of desired pacing rates in order to select the pacing rate of the pacemaker as a function of the measured rate-control parameter.

6.1 In the written procedure, the appellant further argued that the teaching of the present patent consisted essentially in generating a histogram of measured RCP

values and in correlating said histogram with the histogram of desired pacing rates, and that it would have been obvious to a person skilled in the art to apply a principle generally known in the field of automatic control systems (see D1 and appellant's letter of 2 September 1998, pages 4 and 5) to a pacemaker known from D3 or D6. As an example of the use of histograms of measured parameters in the field of pacemakers, the appellant referred to D4.

6.2 D1 is concerned with the problem of developing an automatic control system on the basis of distribution functions. In particular, as pointed out by the appellant, D1 teaches that the simplest way of producing a probability distribution function consists in determining the percentage of time in which a certain signal is below a certain value or above a certain value. However, there is no direct correspondence between the statistical techniques taught in this document and the application of statistical measurements to a rate-responsive heart pacer.

D4 relates to a pacemaker comprising means for producing histograms of certain parameters. However, as submitted by the respondent, such histograms are not used to control the pacemaker in a self-adaptive process.

D6 shows a pacemaker which controls the pacing rate as a function of the measured blood oxygen saturation, so that the greatest possible saturation is achieved with the lowest stimulation frequency. Though the control value used in D6 is both a function of the measured value of the physiological parameter within short time

ranges and a function of the maximum change of such measured values within long time ranges, there is no suggestion that a statistical distribution of the control parameter could be linked to the desired statistical distribution of the pacing rates. As submitted by the appellant, D6 could also be regarded as the starting point of the present invention. However, this document does not show more features of claim 1 of the first auxiliary request than D3.

- 6.3 Though it could be argued, as suggested by the appellant, that it is generally known to represent the input and output variables of a control system in the form of distribution functions, there is no indication in the cited prior art that such principle could be advantageously applied to a rate-control pacemaker, or that a correlation between measured RCP values and a desired pacing rate distribution could be used to control the pacing rate.
7. For the above reasons, it would not have been obvious to a person skilled in the art, starting from the teaching of D3, to arrive at a pacemaker falling within the terms of claim 1 of the first auxiliary request, and, therefore, the subject-matter of this claim involves an inventive step within the meaning of Article 56 EPC.
8. In the result, the Board finds that the respondent's **first auxiliary request** is allowable and that the patent can be maintained on the basis thereof. Consequently, there is no need to consider the respondent's second and third auxiliary requests.



## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain the patent on the basis of the respondent's **first auxiliary request**, as follows:

Claim 1 filed in the oral proceedings of 25 July 2002;

Columns 1 and 2 of the description filed in the oral proceedings and columns 3 to 12 of the description as maintained by the opposition division;

Figures: sheets 1/4 to 4/4 of the patent as granted.

The Registrar:

The Chairman:

R. Schumacher

G. Davies