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DECISION of 18 July 2001

Case Number:

T 0130/97 - 3.4.1

Application Number:

89302973.6

Publication Number:

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A61N 1/365

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Title of invention:

Rate-responsive pacemaker with closed-loop control

Patentee:

TELECTRONICS N.V.

Opponent:

Biotronik Mess- und Therapiegeräte GmbH & Co Ingenieurbüro Berlin

Headword:

Relevant legal provisions: EPC Art. 123(2), 84, 56

Keyword:

"Added subject-matter (no)"

"Inventive step - (yes) after amendment"

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Catchword:



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Beschwerdekammem

Boards of Appeal

Chambres de recours

Case Number: T 0130/97 - 3.4.1

DECISION of the Technical Board of Appeal 3.4.1 of 18 July 2001

Appellant: (Opponent)

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Respondent:

(Proprietor of the patent)

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Decision under appeal:

Interlocutory decision of the Opposition Division of the European Patent Office posted 29 November 1996 concerning maintenance of European patent

No. 0 334 675 in amended form.

Composition of the Board:

Chairman:

G. Davies

Members:

M. G. L. Rognoni U. G. O. Himmler

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal, received on 30 January 1997, against the decision of the opposition division, despatched on 29 November 1996, maintaining European patent No. 334 675 in amended form. The appeal fee was paid on 31 January 1997 and the statement setting out the grounds of appeal was received on 22 March 1997.
- II. The opposition had been filed against the patent as a whole, based on Articles 100(a) and (b) EPC.

The opposition division held that the grounds of the opposition did not prejudice the maintenance of the patent in amended form, whereby the amendments consisted in the deletion of the method claim 25 and of a statement in the description relating to such method claim.

In the contested decision, the opposition division referred, inter alia, to the following document:

D1: EP-A-232 528

- III. Oral proceedings were held on the 18 July 2001.
- IV. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

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

Main request:

Claims 1 to 24 and columns 1 to 47 of the patent specification, with column 3, lines 11 to 13 deleted, and Figures 1 to 30 as granted (as maintained by the opposition division);

First auxiliary request:

Claim 1 filed in the oral proceedings,
Claims 2 to 24, description and Figures as for the main request;

Second auxiliary request:

Claims 1 to 17 filed in the oral proceedings, description and Figures as for the main request.

- V. The wording of claim 1 of the main request reads as follows:
 - "1. A rate-responsive pacemaker (12) including means (190) for periodically ascertaining the value of a measured rate control parameter MRCP (140), said rate control parameter being such that its measured value is changed in one direction by increases in stress/exercise and in an opposite direction by increases in heart rate, and means (48) for generating pacing pulses at a pacing rate greater than or equal to a minimal rate,

characterised by:

means (190) for deriving a target value which is indicative of changes in said MRCP due to non-stress/exercise and non-rate factors, said deriving means being operative when said pacing rate is above said minimum rate to change said target value in a direction which increases the difference between said MRCP and said target value, and said deriving means being operative when said pacing rate is essentially equal to said minimum rate to change said target value

in a direction which decreases the difference between said MRCP and said target value, and means (190) responsive to a change in the difference between MRCP and target value for adjusting said pacing rate in a direction which tends to return said difference to its pre-change value."

Claims 2 to 24 are dependent on claim 1.

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

"1. A rate-responsive pacemaker (12) including means (190) for periodically ascertaining the value of a measured rate control parameter MRCP (140), said rate control parameter being such that its measured value is changed in one direction by increases in stress/exercise if the heart rate does not increase when the patient is under stress and in an opposite direction by increases in heart rate higher than that required for the current state of stress, and means (48) for generating pacing pulses at a pacing rate greater than or equal to a minimum rate, characterised by:

means (190) for deriving a target value which is indicative of changes in said MRCP due to non-stress/exercise and non-rate factors, said deriving means being operative when said pacing rate is above said minimum rate to change said target value in a direction which lowers the pacing rate towards said minimum rate when increasing the difference between said MRCP and said target value and slowly enough such that changes in said MRCP permit rate-responsive operation, and said deriving means being operative when said pacing rate is essentially equal to said minimum rate to change said target value in a direction which decreases the difference between said MRCP and said

target value rapidly relative to said slow change until said target value essentially reaches said MRCP, and means (190) responsive to a change in the difference between MRCP and target value for adjusting said pacing rate in a direction which tends to return said difference to its pre-change value."

Claims 2 to 24 are dependent on claim 1

The wording of claim 1 of the second auxiliary request reads as follows:

"1. A rate-responsive pacemaker (12) including means (190) for periodically ascertaining the value of a measured rate control parameter MRCP (140), said rate control parameter being such that its measured value is changed in one direction by increases in stress/exercise if the heart rate does not increase when the patient is under stress and in an opposite direction by increases in heart rate higher than that required for the current state of stress, means (48) for generating pacing pulses at a pacing rate greater than or equal to a minimum rate, and means (190) responsive to a change in the difference between MRCP and a target value for adjusting said pacing rate in a direction which tends to return said difference to its pre-change value,

characterised by:

means (190) for deriving the target value which is indicative of changes in said MRCP due to non-stress exercise and non-rate factors, said deriving means being operative when said pacing rate is above said minimum rate to change said target value in a direction which increases the difference between said MRCP and said target value such that the pacing rate is lowered towards said minimum rate, and said deriving means being operative when said pacing rate is essentially

equal to said minimum rate to change said target value in a direction which decreases the difference between said MRCP and said target value, wherein:

said target deriving means (190) changes the target value a predetermined small amount, for each MRCP measurement (140), in a direction which tends to lower said pacing rate whenever pulses are being generated above said minimum rate;

said target deriving means (190) changes the target value at a speed which is programmable, but at all times slow enough such that changes in MRCP permit rate-responsive operation;

responsive to said pacing rate being lowered to said minimum rate, said target deriving means (190) changes the target value a predetermined amount relatively larger than said predetermined small amount for each MRCP measurement (140), in a direction which tends to increase said pacing rate until said target value essentially reaches said MRCP; and the speed at which said target deriving means (190) changes the target value in the direction which tends to increase said pacing rate is substantially greater than the highest programmable speed at which said deriving means changes the target value in the

Claims 1 to 17 are dependent on claim 1

direction which tends to lower said pacing rate."

VII. The appellant argued essentially as follows:

Claim 1 of the main request specified that the difference between the measured rate control parameter (MRCP) and the target value was increased when the pacing rate was above the minimum rate. In the embodiment of the invention according to the patent document, however, the target value was actually moved towards MRCP so that the distance between MRCP and

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target value was reduced. Hence, the wording of claim 1 was consistent with the description only if it were assumed that the difference to be increased was expressed by a negative number. On the other hand, "the difference between MRCP and target value" in the context of the correction of the target value effected when the pacing rate equalled the minimum rate had to be interpreted as a positive number which was decreased by bringing the target value closer to MRCP. If the term "difference" in claim 1 were interpreted as meaning simply the "gap" between MRCP and target value, then this claim would relate to a pacemaker which could not be used because an increase in this "gap", when the pacing rate was above the minimum rate, would cause the pacemaker to step up the stimulation rate even further. However, if claim 1 were interpreted as implying an increase of a negative difference between MRCP and target value or a decrease of a positive difference, it would simply reflect the well-known use of a negative feedback loop for the adjustment of the target value in a control system.

Document D1 disclosed a pacemaker with a first negative feedback loop to control the pacing rate and a second negative feedback loop to adjust the target value in the pacing rate control loop. It would be obvious to a person skilled in the art to adjust the parameters of the second feedback loop so as to derive a target value indicative of changes in MRCP due to non-stress - related factors.

Claim 1 of the first auxiliary request and claim 1 of the second auxiliary request were supposed to reflect the illustrative embodiment of the invention specified in the description. However, in this embodiment the target value was actually decreased, and not simply moved in a direction which lowered the pacing rate, and a third "rule", not specified in these claims, was

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applied to account for the fact that a patient might have an intrinsic rhythm higher than the minimum pacing rate. Hence, the independent claims of both auxiliary requests covered pacemakers which were not originally disclosed (Article 123(2) EPC). Furthermore their subject-matters resulted from obvious combinations of the teaching of document D1 and of the skilled person's general knowledge (Article 56 EPC).

VIII. The respondent's arguments may be summarised as follows:

Claim 1 of the main request related to a rateresponsive pacemaker comprising two negative feedback
loops: one loop controlled the pacing rate while the
other one adjusted the target value so as to compensate
for non-stress factors which might influence the MRCP.
Since none of recited documents disclosed or suggested
the use of two negative feedback loops in a rateresponsive pacemaker, the subject matter of claim 1 of
the main request was new and involved an inventive
step.

Claim 1 of the first auxiliary request and claim 1 of the second auxiliary request were based on the illustrative embodiment of the invention specified in the application as originally filed and, thus, were admissible under Article 123(2) EPC.

Claim 1 of the first auxiliary request specified that the increase in the difference between MRCP and target value was intended to lower the pacing rate towards the minimum rate, and that the changes in the target value were slow enough so as not to affect the rate-responsive operation of the pacemaker as a function of MRCP. On the other hand, the target value was changed

rapidly in the direction which decreased the difference between MRCP and target value when the pacing rate had reached the minimum rate. Such features were not known from or suggested by the prior art.

Claim 1 of the second auxiliary request further specified how the target value was actually changed by predetermined amounts according to the rules set out in the description. This combination of features was new and inventive with regard to the cited prior art.

Reasons for the Decision

- 1. The appeal is admissible.
- 2.1 The contested patent relates to a rate-responsive pacemaker which uses a measured rate control parameter (MRCP) to control the pacing rate of the heart as a function of the patient's metabolic needs. According to the description (patent specification, column 1, lines 41 to 46), the depolarisation gradient (i.e. the integral of the QRS segment of an evoked potential) is an excellent MRCP, because this parameter decreases in response to increased stress (including both emotional stress and physical exercise) and increases when the heart is paced at a rate which exceeds the patient's physiological demands.
- 2.2 The control of the pacing rate is carried out by comparing the MRCP with a <u>target value</u>:
 - if the MRCP is smaller than the target value and the heart rate is less than the programmed maximum rate, the pacing rate is increased by some predetermined value;

- if the MRCP increases, thereby indicating a reduction in stress, the rate of stimulation is decreased by some predetermined value.

However, since the MRCP responds not only to stress or physical exercise, but also to factors which do not require an increased cardiac output, a rate control based solely on the comparison of the MRCP with a fixed reference value does not necessarily match the patient's metabolic needs.

2.3 The gist of the present invention consists essentially in changing the <u>target value</u> for the MRCP according to certain rules to compensate for a possible drift in the MRCP due to factors other than emotional or physical stress

"Rule 1"

When the pacing rate is above the minimum rate, it is first assumed that this increase may be due to some non-stress-related factors which may have affected the MRCP so that, even when the patient is resting, this parameter is lower than the target value. In order to compensate for this possible drift in the measurement of the rate control parameter, the target value is slowly decreased until the difference between MRCP and target value allows the pacer's control system to return the pacing rate to the minimum rate. This may happen because the MRCP has in the meantime increased or because the target value has been lowered below the actual MRCP (cf. patent specification, column 11, lines 14 to 39).

"Rule 2"

To account for a drift of the MRCP in the opposite direction or for the fact that, due to a decrease in the target value resulting from the application of "rule 1", the MRCP does not equal the target value at

the minimum pacing rate, the target value is <u>rapidly</u> increased until it reaches the MRCP when the heart is paced at the minimum rate (cf. patent specification, column 11, line 40 to column 12, line 11).

Main request

Interpretation of claim 1

- 3.1 In claim 1, the term "difference between MRCP and target value" occurs:
 - (a) in the context of the feature which is supposed to reflect "rule 1" and which specifies that "when said pacing rate is above said the minimum rate" the target value is changed "in the direction which increases the difference between said MRCP and said target value";
 - (b) in the context of the feature which is supposed to reflect "rule 2" and which specifies that "when said pacing rate is essentially equal to said minimum rate" the target value is changed "in the direction which decreases the difference between said the MRCP and said target value";
 - (c) in the context of the operation of the negative feedback loop which controls the pacing rate, when it is specified that the pacemaker comprises means "responsive to a change in the difference between MRCP and target value" for adjusting said pacing rate in a direction which tends to return said difference to its pre-change value.
- 3.2 According to the appellant, the expression "which increases the difference between said MRCP and said target value" in claim 1 may give rise to an interpretation which is not consistent with the

invention as disclosed in the patent. In particular, while it is clear that a <u>decrease</u> of the difference according to (b) aims at reducing the gap between MRCP and target value, (a) could be interpreted as implying an <u>increase</u> of the difference between MRCP and target value to which the pacemaker has responded by pacing the heart above the minimum rate. Such an increase would cause the pacemaker to stimulate the heart at an even higher rate instead of compensating for a possible drift in the measurement.

- The pacemaker according to the present invention 3.3 controls the pacing rate as a function of the difference between MRCP and target value by means of a negative feedback loop. In other words, the pacer responds to a <u>negative difference</u> (MRCP < target value) by increasing the pacing rate, and to a positive difference (MRCP > target value) by decreasing the pacing rate. The fact that "rule 1" is applied when the pacing rate is above the minimum rate presupposes the existence of a negative difference between MRCP and target value which has caused the pacemaker to increase the pacing rate. According to "rule 1", the negative difference has first to be reduced to zero and then turned into a positive difference in order to bring the pacing rate back to the minimum rate.
- The wording of claim 1 is consistent with the disclosure, and in particular with "rule 1", if it is interpreted as meaning that the target value is changed in a direction which decreases the absolute value of the difference between MRCP and target value, and which thereby increases the negative difference (MRCP- target value), to the effect of lowering the pacing rate. In other words, the feature reflecting "rule 1" implies that an increase in the negative number expressing the

difference between MRCP and target value, when MRCP < target value, results in the target being "lowered" towards the MRCP so that the negative feedback loop of the pacer can respond by decreasing the pacing rate.

On the other hand, "rule 2" is applied when, in response to a <u>positive difference</u> between MRCP and target value, the negative feedback loop has brought the pacing rate back to the minimum rate. Since the target value is supposed to match the MRCP when the patient is at rest, the correction effected by "rule 2" is equivalent to a <u>decrease</u> of any <u>positive difference</u> remaining between MRCP and target value at the minimum pacing rate (cf. patent specification, column 12, lines 12 and 13).

State of the art

- 4.1 It is not contested that D1, which relates to a rateresponsive cardiac pacemaker using the depolarisation
 gradient as measured rate control parameter (MRCP),
 represents the closest prior art. This document
 discloses, inter alia, the following features recited
 in claim 1 of the contested patent:
 - -- means for periodically ascertaining the value of a measured rate control parameter MRCP, said rate control parameter being such that its measured value is changed in one direction by increases in stress/exercise and in an opposite direction by increases in heart rate;
 - -- means for generating pacing pulses at a pacing rate greater than or equal to the minimum rate;
 - -- means responsive to a change in the difference between MRCP and target value for adjusting said pacing rate in a direction which tends to return the difference to its pre-change value.

- According to a first embodiment specified in D1, the target value for a certain measuring cycle is the MRCP measured during the previous cycle. However, D1 (page 11, lines 1 to 4) teaches also that the target value can be the average of three (or of some predetermined number of) previous MRCP's. Furthermore, if the MRCP increases, indicating a reduction in stress, and the pacing rate has reached the programmed minimum rate, the MRCP is stored as target value for the following measuring cycles.
- It is evident to the person skilled in the art that a target value which is represented by the average of previous values of MRCP compensates for a possible drift in the measurements and tends to move closer to the actual MRCP. Furthermore, since a pacing rate above the minimum rate implies a MRCP smaller than target value (i.e. a negative difference between MRCP and target value), moving the target value towards the MRCP increases the negative difference between MRCP and target value. When the minimum pacing rate is reached and the MRCP is stored for use as target value for the next measurement, the difference between MRCP and target value is reduced to zero (i.e. decreased).
- Hence, the subject-matter of claim 1 according to the main request differs from D1 only in that in the former it is specified that the target value is indicative of changes in the MRCP due to non-stress/exercise and non-rate factors.
- It may be argued that D1 does not disclose means for deriving a target value indicative of changes in MRCP due to non-stress/exercise and non-rate factors, because the use of a limited number of previous values of MRCP would not allow long-term non-stress-related factors to be separated from short-term stress-related factors.

5.3 However, it is well known in the art that long-term factors affecting the measurement of a variable with respect to a fixed reference can be compensated for by using as reference the moving average of a larger sample of previously measured values. Thus, it would be obvious to a person skilled in the art, wishing to determine a target value indicative of changes in MRCP due to long-term drift effects, to adapt the system disclosed in D1 by selecting the pre-determined number of previous MRCP's to be averaged so that the resulting target value is only indicative of long-term nonstress/exercise related factors. In so doing, the skilled person would necessarily arrive at a system falling within the terms of claim 1 according to the main request. Hence, in the opinion of the Board the subject-matter of this claim does not involve an inventive step within the meaning of Article 56 EPC.

Admissibility of the auxiliary requests under Article 123(2) and (3) EPC

6.1 The appellant has argued that, although claim 1 of the first auxiliary request and claim 1 of the second auxiliary request are supposed to be based on the embodiment of the invention specified in the application as filed, they recite that the target value is moved in a direction which lowers the pacing rate towards the minimum rate whereas in the description the target value is actually decreased. Furthermore, the means for deriving the target value according to the invention operates not just according to "rule 1" and "rule 2", but also according to a third rule which is not reflected in any of the features of these claims. In the appellant's view, the independent claims of both requests cover pacemakers which do not include all the features of the illustrative embodiment of the invention and, therefore, they are not admissible under Article 123(2) EPC.

- 6.2 As to the appellant's first objection, it is indeed true that in the illustrative embodiment of the invention the target value is decreased whenever the rate is above the minimum rate. In fact, the target value has to be decreased to lower the pacing rate if the parameter used as MRCP (e.g. the depolarization gradient) is such as to cause the pacemaker to increase the pacing rate, whenever the MRCP becomes smaller that the target values. However, it is implicit from the application as filed that the invention is not limited to a particular type of MRCP which, like the depolarisation gradient, decreases when the patient's metabolic demand increases and increases when the heart is paced at a rate exceeding such demand. In the published application, column 1, line 25 to 39, it is specified that the possibility of having a closed loop system is only linked to the fact that the MRCP moves in one direction when the demand increases and in the other direction when the demand decreases so that the closed loop system can operate to adjust the rate in a direction which returns the MRCP to its pre-change value.
- As to the appellant's second objection, the application leaves no doubt that the main problem addressed by the present invention, i.e. the derivation of a target value which reflects changes in MRCP due to non-stress factors, is solved by "rule 1 " and "rule 2", whereas the third rule is intended to deal with the fact that a patient may have an intrinsic rhythm higher than the minimum rate (application as published, column 11, lines 24 to 26 and column 12, lines 31 to 42).
- Hence, in the Board's opinion, claims 1 of the first and second auxiliary requests do not define pacemakers which go beyond the original disclosure and, therefore, they are admissible under Article 123(2) EPC.

7. Both independent claims of the first and second auxiliary requests are based on claim 1 as granted and on features taken from the description or the dependent claims. In particular, claim 1 according to the second auxiliary request is based on the combination of the features specified in claim 1 to 5 as granted. The appellant has not contested the admissibility of these claims under Article 123(3) EPC.

First auxiliary request

Inventive step

- 8.1 Claim 1 according to the first auxiliary request differs from claim 1 according to the main request in that in the former it is further recited that:
 - (a) the MRCP changes in one direction by increases in stress/exercise only "if the heart rate does not increase when the patient is under stress" and it changes in the opposite direction by increases in heart rate "higher than that required for the current state of stress";
 - (b) the target value changes in a direction "which lowers the pacing rate towards said minimum rate when increasing the difference between said MRCP and said target value".

Furthermore the features relating to "rule 1" and "rule 2" are clarified by specifying that:

- the target value is changed "slowly enough so that changes in the said MRCP permit rate-responsive operation"; and

- the difference between said MRCP and said target value is decreased "rapidly relative to said slow change until said target value essentially reaches said MRCP".
- As pointed out above, the determination of the target value in D1 on the basis of previous values of MRCP implies that the target value is effectively moved in a direction which lowers the pacing rate towards the minimum rate by closing the gap which a drift or other factors might have opened between the MRCP and the previous target value. In fact, the target value is moved towards the MRCP whenever the MRCP has a value which causes the pacer to increase the pacing rate above the minimum rate.

When the target value in the pacemaker of D1 is represented by the moving average of previous MRCP's, the changes in the target value are effected slowly enough so that the faster stress-related changes in MRCP still permit a rate-responsive operation.

On the other hand, when the minimum rate is reached and the actual MRCP is stored as target value for the following measuring cycle, the difference between MRCP and target value is decreased rapidly relative to the slow changes effected when the pacing rate is above the minimum rate.

Hence, the only features of claim 1 of the first auxiliary request which are not explicitly disclosed in D1 are the features which distinguish the subject-matter of claim 1 of the main request from the pacemaker of D1. For the same reasons given above, the combination of features recited in claim 1 of the first auxiliary request does not involve an inventive step within the meaning of Article 56 EPC.

Second auxiliary request

Clarity

- 9.1 It is specified in claim 1 that when the pacing rate is above said minimum rate the target value is changed "in a direction which increases the difference between said MRCP and said target value such that the pacing rate is lowered towards said minimum rate"
- The clause "such that the pacing rate is lowered 9.2 towards said minimum rate" is meant to clarify that the target value is moved in a direction which increases the difference between MRCP and target value to which the pacer responds by lowering the pacing rate. As explained above, when the pacer's negative feedback control loop increases the pacing rate as a result of the MRCP being smaller than the target value, the difference between MRCP and target value can be considered to be expressed by a negative number. In this case, the pacing rate is lowered by moving the target towards the MRCP (i.e. by increasing the negative difference between MRCP and target value) and then by bringing the target below the MRCP (i.e. increasing the positive difference between MRCP and target value).
- 9.3 The concept that the initial difference between MRCP and target value responsible for the increased pacing rate is modified in such a way that the pacing rate is lowered whenever it is above the minimum rate is further clarified by the feature that the target value is changed "a predetermined small amount, for each MRCP measurement, in a direction which tends to lower said pacing rate".

Hence, the Board is satisfied that claim 1 complies with the requirements of Article 84 EPC.

Inventive step

- 10.1 Claim 1 according to the second auxiliary request specifies how the target value is changed, and differs from the closest prior art D1 essentially in that:
 - -- the means for deriving a target value indicative of changes in MRCP due to non-stress exercise and non-rate factors changes the target value a predetermined small amount, for each MRCP measurement, in a direction which tends to lower said pacing rate whenever pulses are being generated above said minimum rate;
 - -- said target deriving means changes the target value at a speed which is programmable, but at all times slow enough such that changes in MRCP permit rate-responsive operation;
 - -- responsive to said pacing rate being lowered to said minimum rate, said target deriving means changes the target value a predetermined amount relatively larger than said predetermined small amount for each MRCP measurement, in a direction which tends to increase said pacing rate until said target value essentially reaches said MRCP; and
 - -- the speed at which said target deriving means changes the target value in the direction which tends to increase said pacing rate is substantially greater than the highest programmable speed at which said deriving means changes the target value in the direction which tends to lower said pacing rate.
- As pointed out above, in the pacemaker known from documents D1 the target value can be the average of a predetermined number of previous MRCP's. Although the target value in D1 can get closer to the actual MRCP, it can never become smaller than the actual MRCP and

thus indicate to the control loop that the pacing rate exceeds the patient's metabolic demands. This implies that the pacing rate may stabilize at the level (higher than the minimum rate) which is reached when the target value effectively equals the actual MRCP, since a MRCP matching the target value means for the pacer's control loop that the pacing rate meets the patient's physiological demands and should not be modified.

- 10.3 Starting from document D1, the problem addressed by the present application can be seen in improving the target value deriving means of D1 so as to ensure that the minimum pacing rate can be achieved even if, as a result of drift in the measurement, the MRCP stabilizes below the target value when the patient is at rest.
- 10.4 Claim 1 specifies that the target value is changed by "a predetermined small amount" for each MRCP measurement and that the speed at which the target value is changed is programmable. The fact that the target value is not obtained by averaging previous MRCP's implies that it can be moved below the MRCP so that the difference (MRCP target value) can become positive and thus quickly force the pacing rate back to the minimum rate.
- 10.5 In attacking the inventive step of the subject-matter of claim 1, the appellant has essentially relied on the teaching of D1 and on the skilled person's general knowledge. However, in the absence of any prior art document pointing to the combination of features referred to above (see 10.1), the Board finds that it would not be obvious to a person skilled in the art starting from the teaching of D1 to arrive at a rateresponsive pacemaker falling within the terms of clam 1. Hence, the subject-matter of this claim involves an inventive step within the meaning of Article 56 EPC .

- 10.6 Claims 2 to 17 are dependent and, therefore, their subject-matters also comply with Article 56 EPC.
- 11. For the above reasons, the Board comes to the conclusion that the patent as amended according to the respondent's **second auxiliary request** meets the requirements of the EPC.

Order

For these reasons it is decided that:

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

Claims 1 to 17 filed in the oral proceedings,

Columns 1 to 47 of the patent specification, with column 3, lines 11 to 13 deleted,

Figures 1 to 30 as granted.

The Registrar:

The Chairman:

R. Schumacher

G. Davies

and a relation of the