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D E C I S I O N
of 3 May 1994

Case Number: T 0774/91 - 3.4.1

Application Number: 84304486.8

Publication Number: 0140472

IPC: A61N 1/36

Language of the proceedings: EN

Title of invention:
Stoke volume controlled pacer

Patentee:
Medtronic, Inc.

Opponent:
Biotronik Mess- und Therapiegeräte GmbH & Co.

Headword:
Cardiac Pacer/MEDTRONIC

Relevant legal norms:
EPC Art. 52(4), 54, 56

Keyword:
"Novelty (Main and First Auxiliary Requests - no)"
"Inventive step (Second Auxiliary Request - denied)"

Decisions cited:
-

Catchword:

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0774/91 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 3 May 1994

Appellant: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office dated 24 July 1991 rejecting the opposition filed against European patent No. 0 140 472 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: G. D. Paterson
Members: R. K. Shukla
H. J. Reich

Summary of Facts and Submissions

I. The present appeal lies from a decision of the Opposition Division rejecting the opposition based on Article 100(a) EPC against European patent No. 140 472 relating to a cardiac pacer and a method of controlling the pacing rate of a cardiac pacer. In the Notice of Opposition it was requested that "...the patent be revoked in its entirety since its subject-matter is not patentable pursuant to Articles 52 to 57 EPC ". However, only the objections of lack of novelty and lack of inventive step in the subject-matter of Claim 1 were specifically relied upon and substantiated, having regard to the prior art documents,

D1: DE-A-2 701 104 and
D2: DE-A-3 104 938 (& US-A-4 303 075).

In the following text of this decision, references to document D2 relate to the US document.

II. Independent Claims 1 and 2 of the patent as granted relate to a cardiac pacer whereas independent Claim 7 relates to a method of controlling a pacing rate of a pacer. These claims and Claim 4 as granted have the following wording:

Claim 1

"A cardiac pacer for the therapeutic stimulation of a heart comprising:

a lead system (12) for coupling said pacer (24) to the patient's heart;

a measuring means (20) coupled to said lead system for inferring the stroke volume of said heart from the measurement of a physiologic parameter and for producing

a measurement signal indicative of stroke volume; characterized in that said pacer further comprises

computation and control means (22) coupled to said measuring means for determining a heart rate value in response to said stroke volume measurement signal; and

a pulse generator means (24) coupled to said lead system and said computation and control means for providing stimulation pulses to said heat at a frequency which is a function of said heart rate value."

Claim 2

"A cardiac pacer for the therapeutic stimulation of a heart comprising:

measuring means (20) for periodically inferring the stroke volume of said heart and for producing a set of stroke volume measurements (100);

a pulse generator (24) for providing stimulation pulses to said heart at a frequency dependent on a heart rate value; and characterized in that

means (22) are coupled to said measuring means and coupled to said pulse generator for determining a heart rate value in response to said set of stroke volume measurements."

Claim 4

A cardiac pacer as claimed in Claim 1, 2 or 3 wherein said means for determining a heart rate value comprise:

means (104) for comparing the value of said stroke volume measurement with the value of a stroke volume reference value for producing a stroke volume difference value;

means (106) for determining a heart rate difference value from said stroke volume difference value; and

means (108) for adding said heart rate difference value to the previous heart rate value yielding a current heart rate value."

Claim 7

"A method of controlling the pacing rate of a pacer comprising the steps of:

a) measuring the cardiac stroke volume:

b) comparing the measured stroke volume with a stroke volume reference value yielding a stroke volume difference value: characterised in that said method includes

c) calculating a heart rate difference value from said stroke volume difference value:

d) adding said heart rate difference value to an existing value of heart rate yielding a heart rate summation value:

e) calculating an updated heart rate value from said heart rate summation value: and

f) setting said pacing rate in response to said updated heart rate value."

III. The Opposition Division held that the subject-matter of the opposed patent was not obvious in view of such prior art documents.

IV. In a communication pursuant to Article 110(2) EPC, the Board raised the question whether Claims 7 to 10 define a method which should not be regarded as an invention which is susceptible of industrial application, in accordance with Article 52(4) EPC.

In reply, the patent Proprietor contended that such an objection under Article 52(4) had not been substantiated in the Notice of Opposition and was a fresh ground of opposition within the meaning of Decision G 10/91, OJ

EPO 1993, 408 and 420, and that following what is stated in paragraph 18 of the Decision, the patent Proprietor did not agree to the introduction of such fresh ground in the appeal proceedings. The patent Proprietor in any event denied the validity of the objection. The Opponent denied that such objection was a fresh ground of opposition, and asked the Board to decide upon such objection.

V. Oral proceedings were held on 3 May 1994.

VI. The Opponent submitted essentially the following arguments in relation to the question of inventive step:

The decision of the Opposition Division is mainly based on the view that a change in AV delay is not to be regarded as a change in stimulation rate, since a change in VA delay in the opposite direction could compensate the change in the AV delay. In the apparatus of document D2, however, no measures are apparent which could compensate for changes in VA delay. As the apparatus of document D2 makes use of a "conventional pacer" (unit 36 in Figure 1) such as described in document D1, which is synchronised with a ventricle contraction, a change in AV delay leads to a change in the heart rate. The claimed subject-matter thus does not involve an inventive step in relation to a combination of the disclosures in documents D1 and D2.

Claim 1 of an Auxiliary Request containing features of Claims 1 and 4 as granted also does not provide a solution having any inventive merit since in document D2 a procedure to determine a stroke volume difference value is disclosed which is analogous to that in the patent in suit (see units 18, 20 and 22 in Figure 1). In document D2, the stroke volume difference value is derived from the current and the previous values of the

stroke volume, a heart rate or AV delay difference value is derived from the stroke volume difference value using a known relationship and this heart rate difference value is added to a the previous heart rate value. Although in document D2, mainly the direction of variation of stroke volume is evaluated and utilized, it is evident to a skilled person having regard to the calibration curve shown in Figure 2 of document D2 that the actual stroke volume difference value can also be utilised in an analogous manner.

VII. The patent Proprietor presented essentially the following arguments in support of an inventive step in the claimed subject-matter:

The system disclosed in document D2 measures the instantaneous stroke volume and varies the AV-delay such that the stroke volume is maximised "independently of .... heartrate calculations" (see column 2, lines 66 to 68). The atrial and ventricular escape intervals are fixed in document D2, so in the absence of natural heart activity the pacing rate is essentially constant. Document D2 thus does not disclose a rate adaptive pacer having a computation and control means for determining a heart rate value in response to the stroke volume measurement signal but a method and apparatus for maximising the stroke volume at an essentially constant heart rate. Using the system according to the patent in suit, when the patient requires an increase in cardiac output both the heart rate and the stroke volume can be increased providing the required output without undue strain.

VIII. The Opponent requested that the decision of the Opposition Division be set aside and the patent be revoked in its entirety.

The patent Proprietor requested that the appeal be rejected and the patent be maintained in the form as granted. As a First Auxiliary Request it was requested to maintain the patent on the basis of Claim 1 as filed during the oral proceedings before the Board, in which the computation and the control means are stated to be "for generating a heart rate value" instead of "for determining a heart rate value". As a Second Auxiliary Request it was requested to maintain the patent on the basis of a new Claim 1 containing features of Claims 1 and 4 as granted.

IX. At the conclusion of the oral proceedings, the decision was announced that the Decision of the Opposition Division is set aside and the European patent is revoked.

Reasons for the Decision

1. *Main Request - Claim 1*

1.1 Document D2 describes an atrioventrical (AV) pacer for maximising stroke volume through atrioventricular pacing, wherein the spacing or interval between the atrial and ventricular pulses (AV delay) is increased or decreased in accordance with detection of increasing or decreasing stroke volume as measured from one heart cycle to the next (see column 2, line 60 to column 3, line 6). The AV pacer (10) comprises a pair of electrodes (12,13) connected to an impedance processor (16) measuring impedance of the heart which varies between a minimum value and a maximum value during a heart cycle. The analogue signal from the impedance processor representing the difference between the maximum and minimum values of the impedance is proportional to the stroke volume of the heart and is

applied to peak-to-peak impedance change detector 18. The voltage output of the detector (18) approximates the stroke volume of the heart (see column 4,lines 6 to 46 and Figure 1).

The prior art AV pacer according to document D2 thus has all the features as set out in the precharacterising part of Claim 1 of the main request.

Moreover, in the AV pacer of document D2 (see, in particular, column 4, line 49 to column 5, line 40) in response to the voltage output of the detector (18), the AV pulse delay set in AV pulse delay generator (32) is varied (increased or decreased) by means of up-down counter (28) under the influence of flip-flop 26. The AV pulse delay generator, under the influence of a conventional pacer (36), generates an atrial pulse if the atrial escape interval has been exceeded, which atrial pulse is provided to the atrial pacing electrode (14). Then, based on the AV delay provided to the generator (32) by the counter (28), the generator generates a ventricular trigger pulse which is converted to a pacing pulse and is provided to the ventricular pacing electrode (15).

1.2 In its decision, the Opposition Division held that in document D2 only AV delay is changed, and since VA delay could change in opposite direction to the direction of change in AV delay, the heart rate could remain fixed. In the Board's view, however, document D2 discloses that the atrial stimulation pulses are always applied "if the atrial escape interval has been exceeded" (see column 5, lines 15 to 18), which means that the atrial stimulation pulses are applied after a fixed VA delay. Since delay between the issuance of atrial pulse and the ventricular pulse(AV delay) is varied, and since VA delay is fixed, it follows that the rate at which successive atrial or

ventricle pulses are applied to the heart is also varied. In other words, a variation in the AV delay in combination with a constant VA delay necessarily results in a change in the frequency at which the heart is stimulated by the conventional pacer of document D2. This was not disputed by the patent Proprietor.

The up-down counter (28) in document D2 counts in the same direction as during the preceding heart beat or in the opposite direction depending on whether the new impedance swing value exceeds or is less than preceding impedance swing value, respectively, so that the counter performs mathematical operations of addition and subtraction. Contrary to the submission of the patent Proprietor, the electrical circuit of document D2 comprising the comparator (22), selector (34), flip-flop (26), up-down counter (28), conventional pacer (36), and AV pulse delay generator (32), therefore represents "computation and control means" specified in the characterising part of Claim 1 and, in the terminology employed in the claim, "are coupled to said measuring means for determining a heart rate value in response to said stroke volume measurement signal". Moreover, as follows from Figure 1 of document D2 the conventional pacing pulse generators (38 and 40)are coupled to the "computation and control means" and "to the lead system" and thus supply stimulation pulses to atrial and ventricular pacing electrodes "at a frequency which is a function of said heart rate value".

1.3 In view of the above, in the Board's judgment, the prior art AV pacer as described in document D2 falls within the terms of claim 1 of the main request, so that its subject-matter is not new within the meaning of Article 54 EPC.

2. *Main Request - Independent Claim 2*

Claim 2, although worded differently to Claim 1, differs in substance from the latter only in that it specifies that the measuring means are for periodically inferring the stroke volume of the heart and that they produce a set of stroke volume measurements.

The AV pacer of document D2 is also provided with an actuator (42) which in a "timer" mode operation periodically issues actuation command signals to the impedance processor and the up-down counter to provide a set of impedance measurements representing stroke volume values (see column 5,lines 42 to 58). The subject-matter of Claim 2 is therefore not new.

3. *First Auxiliary Request*

Also in the Board's judgment, Claim 1 according to First Auxiliary Request is not new with respect to the prior art document D2, since a new AV delay, and therefore a new heart rate value, is "**generated**" by the AV pulse delay generator (32) in response to a change in the heart impedance representing a change in the stroke volume.

4. *Second Auxiliary Request*

4.1 As mentioned earlier in section 1.1 above, in the AV pacer according to document D2, the output of peak-to-peak impedance change detector (18) representing the stroke volume of the heart is compared with that of the last impedance change latch (20) indicative of the preceding stroke volume in a comparator (22). The comparator output, however, does not represent stroke volume difference value as required by the wording of Claim 1, but is merely indicative of whether the stroke

volume is increasing or decreasing. Also, there is no determination of a heart rate difference value using the stroke volume difference value.

In the AV pulse delay generator (32), a desired AV pulse delay representing a specific heart rate value is set by the up-down counter (28), and the set value is increased or decreased by the counter (28) under the influence of the flip-flop (26). A heart rate difference value is however not added to the set value to provide a current heart rate value as required by the wording of Claim 1.

The cardiac pacer according to the claimed invention is thus distinguished over the AV pacer of document D2 in that it is provided with (a) means (104) for producing a stroke volume difference value, (b) means (106) for determination of a heart rate difference value using the stroke volume difference value and (c) means (108) for addition of the heart rate difference value to the previous heart rate value to obtain a current heart rate value.

4.2 In support of an inventive step in the claimed subject-matter, it was argued by the patent Proprietor (see page 2, paragraphs 2 and 3 of the Statement of Ground of Appeal) that in the patent under dispute stroke volume measurement is used to control the heart rate thus producing a cardiac output appropriate to the patient's current requirement. It was further submitted that using the present system, when the patient required an increase in cardiac output both the heart rate and the stroke volume could be increased providing the required output without undue strain.

In this connection, as pointed out in section 1.2 above, in the AV pacer according to document D2 also a stroke volume measurement is used to control the AV delay and

therefore the heart rate, albeit only during a period when the stroke volume is maximised. As to producing a cardiac output appropriate to the patient's requirement, the wording of Claim 1 does not specify that the heart rate is **increased** in response to **an increase in the stroke volume**, so that the cardiac pacer as claimed does not necessarily operate to increase the cardiac output, when there is such a demand due to physical exertion, by increasing the heart rate in response to an increase in the stroke volume.

The measures which distinguish the claimed invention from the AV pacer according to document D2 (see section 4.1 above), also do not contribute towards adapting the heart rate to body's demand for **higher** cardiac output but merely determine a new heart rate value in response to a value representing a difference in stroke volume. In the assessment of inventive step, it is well established that technical effects are to be taken into account only to the extent they are directly caused by the technical features of the claim, so that in the present case the alleged effect of the claimed cardiac pacer, namely, adaptation of the cardiac output to the current requirement of the patient, cannot be taken into consideration.

4.3 In contrast to an iterative control technique used in the AV pacer of document D2 to control the AV delay, and therefore, the heart rate, in response to a change in the stroke volume measurement, a different control technique as set out in the distinguishing features (a) to (c) is employed in the claimed invention. In the Board's view, as correctly argued by the Opponent, the control steps, per se, as defined in features (a) to (c) are conventional and analogous to the ones employed in document D2, so that for a skilled person concerned merely with the determination of a current heart rate in

response to a variation in the stroke volume (and not with maximising a stroke volume as in document D2),their application in the cardiac pacer of document D2 was obvious.

For the foregoing reasons, in the Board's judgment, the subject-matter of the claimed invention does not involve an inventive step within the meaning of Article 56 EPC.

5. As the patent Proprietor's requests do not comply with the requirements of Articles 54 or 56 EPC as discussed above, the patent is to be revoked. There is, therefore, no need to consider the matter mentioned in paragraph IV above.

Order

For these reasons it is decided that:

1. The Decision of the Opposition Division is set aside.

2. The European Patent is revoked.

The Registrar: The Chairman:

M. Beer G. D. Paterson