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D E C I S I O N
of 14 February 1995

Case Number: T 0537/93 - 3.4.1

Application Number: 84102590.1

Publication Number: 0121794

IPC: A61N 1/36

Language of the proceedings: EN

Title of invention:
Pacemaker with switchable circuits and method of operation of same

Patentee:
VITATRON MEDICAL B.V.

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

Headword:
Pacemaker/VITATRON

Relevant legal provisions:
EPC Art. 56, 83
EPC R. 67

Keyword:
"Inventive step - yes (after clarifying amendments)"
"Disclosure of the invention - sufficiently clear and complete (yes)"
"Procedural violation during the opposition proceedings (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0537/93 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 14 February 1995

Appellant: (Opponent)
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Decision under appeal: **Interlocutary decision of the Opposition Division of the European Patent Office dated 2 April 1993 concerning maintenance of European patent No. 0 121 794 in amended form.**

Composition of the Board:

Chairman: G. D. Paterson
Members: R. K. Shukla
U. G. M. Himmler

Summary of Facts and Submissions

I. European patent No. 0 121 794 relating to a pacemaker with microprocessor control means for controlling the frequency characteristics was opposed on the ground that the subject-matter of the patent did not fulfil the requirements of Article 52 EPC as required by Article 100(a) EPC. In the notice of opposition, the objections of lack of novelty and inventive step were substantiated having regard to the document EP-A-0 057 944. Furthermore, the Opponent submitted that the claimed invention was not so clearly disclosed that it could be carried out by a person skilled in the art (Article 100(b) EPC).

The Opposition Division introduced, inter alia, the following additional documents during the opposition proceedings:

D3= US-A-4 228 803

D4= US-A-4 381 786,

and maintained the patent in amended form.

II. The only independent claim, which formed the basis of the decision of the Opposition Division, has the following wording:

"A cardiac pacemaker having a sense circuit for amplifying sensed cardiac signals, said circuit having an output and switchable to at least two respective frequency characteristics (65, 66, 70), each of said characteristics enabling a signal response at said output while it is switched to said characteristic, means for monitoring the signal response of said circuit

over a predetermined number of pacemaker cycles and determining a measure of said response over said cycles (285, 286, 287), microprocessor control means (Figs. 2A, 2B) for changing at least one of said frequency characteristics each cycle as a function of said measure (289, 290, 291), wherein said microprocessor control means further controls the frequency characteristic of said input amplifier to have respective different frequency characteristics during sensing of evoked QRS (263) and T-wave (274) portions of each sensed cardiac signal."

III. According to the above decision, the subject matter of Claim 1 was considered to be clear, novel and to involve an inventive step. In particular, the Opposition Division held that although in document D4 the frequency response of an input amplifier of a pacemaker is adjusted to match physiological needs of a patient, this adjustment is done statically and the frequency response of the input amplifier is not changed on a cyclical basis. Therefore, the application of the teaching of document D4 to the pacemaker known from document D3 does not lead to the claimed invention.

IV. The Opponent lodged an appeal against the above decision and requested that the patent be revoked in its entirety, since the claimed subject matter does not involve an inventive step with regard to the documents cited during the proceedings before the Opposition Division and the following additional documents:

D5= "The Software Pacemaker" by J. Buffet et al.; "Cardiac Pacing", Piccin Medical Books 1982, pp. 1273-1276,

D6= "Input Filters of Pulse Generators; Are they optimal?" by M.I.Sedney et al.; "Cardiac Pacing", Piccin Medical Books 1982, pp. 1295-1301.

The Appellant further submitted that the claimed invention contravenes Article 83 EPC. Reimbursement of the appeal fee under Rule 67 EPC was also requested by the Appellant.

V. The Respondent (Proprietor of the patent) requested dismissal of the appeal.

VI. In response to a communication from the Board stating its preliminary opinion that Claim 1 did not fulfil the requirements of Articles 84, 123(2) and (3) EPC, the Respondent filed amended Claims 1 and 2 on 15 September 1994.

VII. During the oral proceedings, which were held on 14 February 1995, the Respondent filed further Claims 1 and 2 replacing the earlier Claims 1 and 2 filed on 15 September 1994. The only independent Claim 1 filed at the oral proceedings has the following wording:

"A cardiac pacemaker having
- an input amplifier (Fig. 1) for amplifying sensed cardiac signals,
- said input amplifier having multiple parallel output circuits which each comprises a switch (70) and a filter (65, 66) having a particular frequency response characteristic enabling a particular frequency characteristic of said input amplifier and thus a particular signal response at the corresponding output while the corresponding switch is activated,
- microprocessor control means (Fig. 2B) for controlling the frequency characteristic of said input amplifier on a cyclical basis to have respective

different frequency characteristics during sensing of evoked QRS complex (263) and T-wave (274) portions of each sensed cardiac signal, and

- means (Fig. 2C) for monitoring a particular signal response of said input amplifier over a predetermined number of unevoked cycles and determining a measure of the amplitudes of said response over said cycles (285, 286, 287),
- said microprocessor control means comprising means (Fig. 2C) for shifting the corresponding particular frequency characteristic of the input amplifier as function of said measure (289, 290, 291)."

VIII. The Appellant presented essentially the following arguments in support of its request.

(a) Article 83 EPC

The wording of Claim 1 of the patent in suit contains vague expressions, such as "a sense circuit for amplifying", and unclear references so that there is no clear relationship between the device features of Claim 1 and those of the invention as described. Also there is no clear disclosure in the patent in suit of the intervals during which different frequency characteristics are selected, and it is not described how the start of a cycle and its duration are determined. Furthermore, the description does not contain an example of the filter characteristics mentioned in the claim. An evoked QRS signal is different from a natural QRS signal, but nevertheless the description does not contain any constructional details of the input amplifier so that it can detect different types of QRS signal. The patent thus does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a skilled person.

(b) Inventive step

Document D3 discloses a demand pacemaker which has a QRS detector (15), a T-wave detector (25) and switching means (16, 26) for switching between these detectors. Document D6 discloses the use of adjustable high- and low-pass filters (see page 1295) and recommends the use of a detector tuned to a particular frequency. It would therefore be obvious to the skilled person to modify the pacemaker disclosed in document D3 to have a single detector, the frequency characteristic of which can be controlled such that both the QRS complex and the T-wave can be detected by a single detector. Furthermore, the use of a microprocessor means to control the pacemaker is well-known in the art, as exemplified by D5, and thus obvious to the skilled person.

(c) Reimbursement of the appeal fee

The subject-matter of the invention according to Claim 1 forming the basis of the decision of the Opposition Division differs considerably from that discussed in the assessment of inventive step in item 14, second paragraph of the decision. The Opposition Division has therefore committed a substantial procedural violation which justifies reimbursement of the appeal fee according to Rule 67 EPC.

IX. The Respondent presented essentially the following arguments in support of its request.

(a) Article 83 EPC

The expressions in the claim which have been objected to by the Appellant are well-known in the art. Also the input amplifier and the technique of switching between different amplifier frequencies are conventional per se.

so that the skilled person would have no difficulty in carrying out the invention as claimed. The description in connection with Figure 1, in particular, discloses the construction of the input amplifier circuit. Since the T-wave signal occurs after the evoked QRS signal it is possible to distinguish between the two signals. Figure 2 B shows where in the cycle the filter is set to sense the evoked QRS complex and the T-wave, respectively. Figure 2 C and the corresponding part of the description disclose how to determine a measure of the amplitudes over several cycles. The patent therefore clearly teaches the skilled person how to carry out the invention.

(b) Inventive step

Document D3 describes separate QRS and T-wave detectors so that it in fact leads away from the solution taught in the present invention. Document D6 supports the patentability of the present invention, since it suggests a first band- pass filter to detect the QRS complex only, and then states that T-wave sensing is not likely to occur with such a filter (page 1298). Document D6, therefore, does not teach to switch the filter between different characteristics.

X. At the conclusion of the oral proceedings it was announced that the decision of the Opposition Division is set aside, and that the case is remitted to the first instance with the order to maintain the patent on the basis of Claims 1 and 2 as filed at the oral hearing.

Reasons for the Decision

1. *Article 83 EPC*

1.1 In the patent in suit, the input amplifier circuit of a cardiac pacer is described with reference to Figure 1 in column 2, line 45 to column 3, line 61. According to the description (see, in particular, column 3, lines 34 to 38) the output circuit of the input amplifier comprises a capacitor 65, a resistor 66 and a switchable FET 70. In column 4, lines 44 to 48 and 60 to 64 it is stated that a switchable filter, which can be set to different settings, is constructed as disclosed in Figure 1 but with a multiple of parallel output circuits. It is thus clear to the skilled person that the switchable frequency characteristic of the input amplifier defined in Claim 1 can be obtained by the construction as disclosed in Figure 1 but with a plurality of output circuits. Furthermore, in the Board's view, the skilled person using the resistor and capacitor values disclosed in column 3 as a reference and using his normal constructional skills would be able to determine the values for the capacitors and the resistors in the multiple parallel output circuits in order to arrive at switchable frequency characteristics suitable for sensing the evoked QRS signal and T-wave.

1.2 Figure 2 B shows where in the pacemaker cycle the filter is switched to receive the evoked QRS complex and the T-wave, respectively. Furthermore, in the Board's opinion, it lies within the competence of the skilled person to determine the specific filter characteristics required for the sensing of the evoked QRS complex and the T-wave portions of the cardiac signal and to select the output circuits of the input amplifier accordingly.

1.3 Figure 2 C shows a flow diagram for monitoring and storing amplitude of the input signal over a predetermined number of cycles (288), and the description corresponding to Figure 2C in column 5, lines 26 to 65 describes the determination of a measure of the amplitude over said cycles. According to the description, the central frequency of the filter is shifted as a function of the measure of the amplitudes. It is also clear both from Figure 2 C (reference numbers 250 and 251) and from column 5, lines 11 to 16 that the flow diagram routine of Figure 2 C is to be inserted in the left hand branch of the flow diagram of Figure 2A between boxes 250 and 251. It further follows from column 4, lines 11 to 18 and Figure 2 A that the routine of Figure 2C is carried out if a natural QRS signal has been detected before a time-out has occurred (238). It is therefore clear that the description of the flow diagram of Figure 2C concerns natural or unevoked heart beats. The skilled person thus learns from the flow diagrams of Figures 2 A and 2C how to implement the features of Claim 1 relating to monitoring and storing of amplitude of unevoked cycles and shifting of the frequency of the input amplifier as a function of the amplitude.

1.4 Electric filter circuits, their designing and microprocessor control techniques in general belong to the basic technical knowledge of a person skilled in the art of cardiac pacemaker, so that the Board, contrary to the submission of the Appellant, is of the view that the skilled person would be able to design filters having frequency characteristics suitable for detecting evoked and natural (i.e. unevoked) heart signals and to control switching of frequency characteristics with the help of a microprocessor.

1.5 In view of the above considerations, in the Board's judgment, the skilled person was in a position to carry out the claimed invention on the basis of the disclosure in the patent in suit at its filing date, so that the requirement of Article 83 EPC is met.

2. *Inventive step*

2.1 Document D3, which constitutes the closest prior art, is concerned with a cardiac pacemaker having a circuit for controlling the pacing rate in relation to physiological changes, the circuit detecting an evoked T-wave following a delivered stimulus pulse and measuring the time interval between the stimulus pulse and the following evoked T-wave (see the abstract and column 1, line 64 to column 2, line 5). The circuit has a QRS detector (15) for detecting the spontaneous QRS complex of an intrinsic heart activity and a T-wave detector (25) (see column 2, lines 34 to 59). On application of a stimulus pulse to the heart, a switch (16) is opened for a predetermined period which is greater than the interval between the delivery of stimulus pulse and the QRS complex of the evoked signal, so that the QRS detector remains disconnected from an electrode (13) for sensing the cardiac signals and the QRS complex of the evoked signal is not detected during the predetermined period following the application of the stimulus pulse.

Document D3 does not explicitly mention input amplifiers for the detectors and their filter characteristics, but as their names suggest, the detectors must have input amplifiers with suitable frequency characteristics so as to detect the spontaneous or intrinsic QRS complex and the evoked T-wave portion, respectively.

2.2 The subject matter of Claim 1 under consideration is thus distinguished over the above prior art in the following:

(a) there is a common input amplifier for the detection of the evoked QRS and the T-wave signals;

(b) the input amplifier has multiple output circuits, each comprising a switch and a filter enabling a particular frequency characteristic of the amplifier when a corresponding switch is activated;

(c) microprocessor control means is provided for controlling the frequency characteristic of the input amplifier so that the latter has respective different frequency characteristics during sensing the evoked QRS complex and the T-wave portion of a cardiac cycle;

(d) means are provided for monitoring a particular signal response over a predetermined number of unevoked cycles and determining a measure of the amplitudes of said response over said cycles; and

(e) the microprocessor means comprises means for shifting the frequency characteristic of the input amplifier as a function of said measure.

2.3 The cardiac pacemaker as set out in the distinguishing features (a) to (b) employs a single common input amplifier for sensing both the evoked QRS signal and the T-wave portion instead of two separate detectors for the spontaneous QRS complex and the evoked T-wave, respectively, as in document D3. These features thus enable one to design a relatively compact cardiac pacemaker. It further follows from the features (b) to (e) that whereas for an evoked QRS signal the input

amplifier is switched to an appropriate frequency characteristic, for an unevoked cardiac signal, the frequency characteristic of the input amplifier is shifted as a function of the amplitude of the unevoked cardiac signal determined over several cycles. This special measure for the detection of an unevoked cardiac signal, e.g. an unevoked QRS signal, in the Board's view, takes into account the fact that unevoked and evoked QRS signals differ considerably in their respective frequency ranges and therefore require different measures for detecting them.

The objective problem underlying the present invention therefore can be seen as providing a pacemaker which is relatively compact and has improved response to evoked and intrinsic or unevoked cardiac signals.

2.4 Document D6 discusses the problem of over sensing the T-wave and undesirable signals when the QRS complex is to be detected (see page 1295, left column; page 1298, left column) and discloses (see page 1295, right column, last paragraph) that adjustable filters were used to appraise the optimal frequency range for sensing the intrinsic deflection, i.e. QRS complex. The document accordingly stresses the need for accurately tuning the filter in order to avoid the detection of signals other than the QRS complex (page 1298, "Discussion"; page 1301, "Summary"). There is however no suggestion in the document that the filter should be switchable such that it, on a cyclical basis, can detect both the evoked QRS complex and the T-wave and that a common input amplifier should be used for such detection. Moreover, document D6 does not describe different measures for the detection of evoked and unevoked QRS complexes, respectively.

2.5 In relation to the detection of the unevoked QRS complex as in features (d) to (e), it was submitted by the Appellant that it is common general knowledge in the field of cardiac pacemaker that the evoked and unevoked QRS complexes differ considerably in their frequency ranges, so that a skilled person would have routinely used a detection technique for the unevoked QRS complex as in features (d) to (e). The Board, however, does not agree with the above submission since despite the fact that unevoked and evoked QRS complexes are known to be different, none of the cited documents D3 and D6 teaches a detection technique as claimed, for the unevoked cardiac signal and that too in combination with the detection of an evoked QRS complex, for the purpose of improving the response of the cardiac pacemaker. Therefore, in the Board's view, the skilled person would not be led by the teaching of document D6 to modify the pacemaker disclosed in document D3 to include features (d) to (e) in combination with the detection of evoked signals.

In relation to feature (a) mentioned above, even if the skilled person considered combining the QRS detector (15) and T-wave detector (26) of document D3 in a common detector with appropriate switchable frequency characteristics, this would lead to detection only of the spontaneous or intrinsic QRS complex and not of the evoked QRS complex (see paragraph 2.1 above).

2.6 Document D5 is concerned with the use of microprocessor in pacemaker circuits and is not relevant in so far as the features (d) to (e) are concerned. It is also to be noted that document D4, which was discussed in the decision of the Opposition Division, does not belong to the state of the art according to Article 54(2) EPC and is thus not relevant to the issue of inventive step.

2.7 For the foregoing reasons, in the Board's judgement, the subject matter of Claim 1 fulfils the requirement of inventive step within the meaning of Article 56 EPC.

3. *Reimbursement of the appeal fee*

The Appellant's request for the reimbursement of the appeal fee, in the Board's view, is not well founded and cannot be allowed for the following reasons .

In item 14, paragraph 2 of the decision of the Opposition Division, it is stated that, "Claim 1 relates to a microprocessor controlled rate adaptive pacemaker which comprises an input amplifier which can be set to different frequency responses for optimally monitoring the two physiological parameters, evoked QRS and T-waves by specially adapted frequency response characteristics". Although the Board notes that the cardiac pacemaker according to Claim 1 forming the basis of the decision was not restricted to a rate adaptive pacemaker as stated in the above statement, in the Board's view, it is evident from the remaining text of the statement that the assessment of inventive step was based solely on different frequency characteristics for the evoked QRS and T-waves, respectively, of the input amplifier. This feature of the input amplifier was clearly a part of the claimed subject-matter.

Order

For these reasons it is decided that:

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

2. The case is remitted to the first instance with the order to maintain the patent on the basis of Claims 1 and 2 filed during the oral hearing.

The Registrar: The Chairman:

M. Beer G. D. Paterson