

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen
(D) [] No distribution

D E C I S I O N
of 9 May 2001

Case Number: T 0924/96 - 3.4.1

Application Number: 89106279.6

Publication Number: 0338364

IPC: A61N 1/362

Language of the proceedings: EN

Title of invention:

Lead impedance scanning system for pacemakers

Patentee:

St. Jude Medical AB

Opponent:

BIOTRONIK Mess- und Therapiegeräte GmbH & Co. Ingenieurbüro
Berlin

Headword:

Lead impedance scanning system for pacemakers/ST JUDE MEDICAL
AB

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 0924/96 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 9 May 2001

(Opponent)

BIOTRONIK
Mess- und Therapiegeräte GmbH & Co
Ingenieurbüro Berlin
Woermannkehre 1
D-12359 Berlin (DE)

Representative:

Eisenführ, Speiser & Partner
Pacelliallee 43/45
D-14195 Berlin (DE)

Respondent:

(Proprietor of the patent)

St. Jude Medical AB
SE-175 84 Järfälla (SE)

Representative:

Harrison, Michael Charles
Albihns GmbH
Grasserstrasse 10
D-80339 München (DE)

Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted 1 August 1996
rejecting the opposition filed against European
patent No. 0 338 364 pursuant to Article 102(2)
EPC.**

Composition of the Board:

Chairman: G. Davies
Members: H. K. Wolfrum
M. G. L. Rognoni

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the decision of the Opposition Division, dispatched on 1 August 1996 rejecting the opposition against European patent No. 0 338 364. The notice of appeal was received on 8 October 1996, the prescribed fee being paid on the same day. The statement setting out the grounds of appeal was received on 25 November 1996.
- II. Opposition had been filed against the patent as a whole and based on the grounds of Articles 100(a) and 100(b) EPC and substantiated on the grounds of insufficiency of disclosure (Article 83 EPC) and lack of inventive step (Articles 52(1) and 56 EPC).
- III. In a communication dated 11 January 2001 and annexed to a summons to attend oral proceedings, the Board expressed its preliminary opinion that the appellant's submission under Article 83 EPC did not appear to be pertinent. The Board considered the arguments submitted in support of this submission to relate to ambiguities as regards the solution of the posed problem and the functioning of the claimed apparatus, which, however, concerned the issue of clarity (Article 84 EPC) not being a ground of opposition and not to be discussed in the context of claims as granted.
- IV. The only point of discussion in the oral proceedings which were held on 9 May 2001 was the issue of inventive step.
- V. The appellant requested that the decision under appeal be set aside and that the patent be revoked. Reference was made to the following documents:

D1: FR-A-2 369 836,

D2: GB-A-2 026 870,

D3: US-A-4 527 567,

D4: US-A-4 702 253, and

D5: US-A-4 493 325.

VI. The respondent requested that the appeal be dismissed and, as the main request, that the patent be maintained as granted. Alternatively, it was requested to maintain the patent on the basis of one of four auxiliary requests.

VII. Independent claims 1 and 13 of the patent as granted reads as follows:

"1. A lead impedance scanning apparatus (40) for an implantable stimulation device (10) comprising: means (54,62) for making lead impedance measurements during operation of the device (10), said means (54,62) including means (50) for determining the energy delivered to a stimulation lead (46) during a stimulation pulse; means (80,134) for comparing said impedance measurements with at least a preselected reference; and means (56) responsive to the detection of measurement deviations which deviate from said preselected reference by a predetermined amount for indicating the occurrence of a change in lead impedance characterized in that said preselected reference is established by means

(R1,C3) for developing a moving average of impedance measurements."

"13. A method of discovering defective leads of an implantable stimulation device comprising the steps of: making lead impedance measurements during operation of the device, whereby the energy delivered to a stimulation lead is determined during a stimulation pulse; comparing said impedance measurements with at least a preselected reference; and noting the occurrence of measurement deviations which deviate from said preselected reference by a predetermined amount characterized by the step of developing a moving average of impedance measurements as said preselected reference for comparison with individual impedance measurements."

VIII. Starting from document D1 as the closest prior art, the Opposition Division considered the object of the invention to lie in using the signals encountered in the normal operation of an implanted pacemaker in the process analysis to detect deviations and departures from the signal norm to indicate the occurrence of such. The Division observed that documents D1 and D2 referred to the monitoring of the impedance of stimulation leads but did not hint at comparing the results with a moving average of impedance measurements, whereas documents D4 and D5, although teaching to use a moving average of some parameter values in a pacemaker for the purpose of a reference, did not relate to any lead impedance scanning apparatus. In consequence, the presence of an inventive step was seen in the fact that none of documents D1 to

D5 hinted at the basic principle of comparing a monitored lead impedance with a reference, which was established by means for developing a moving average of lead impedance measurements.

IX. The appellant essentially relied on the following submissions:

The subject-matter of independent claims 1 and 13 resulted from a straightforward combination of the teaching of either document D1 or D2 with that of D4 or D5 as all documents referred to the same technical field of pacemakers. The sole difference between the subject-matter of said claims and the teaching of D1 or D2 resided in the provision of means for developing a moving average of impedance measurements and the step of developing such an average, respectively, for use as the preselected reference. This feature allowed for instance for a compensation of long-term drift effects occurring in the measurements.

Thus, the objective problem to be solved was to be seen in the desire to compensate for observed deviations of impedance measurements from a preselected reference due to long-term drift effects which may occur in the electronic circuitry of the implantable stimulation device and/or in the physiological reaction of a patient to said circuitry. However, this problem as well as the claimed solution were known from each of D4 and D5. In this context, further evidence as to the fact that electronic circuits of pacemakers indeed showed drifts was available from document D3.

On the other hand, an assessment of inventive step was impeded by the fact that it was not quite clear what

exactly was the subject-matter of the invention. The opposition division had recognized an inventive step without reflecting on whether or not the claimed means provided a meaningful and working solution to a technical problem.

IX. The respondent disputed the appellant's view, relying essentially on the following arguments:

The true objective problem over the prior art was the accurate detection of anomalies in a stimulation lead providing significant but gradual variations indicative of impending lead failure.

This problem could not be solved by the teachings of documents D1 and D2 because these documents, although relating to measurements of the lead impedance of a pacemaker stimulation lead, were not concerned with the determination of gradual impedance changes but only with establishing whether the measured lead impedance was inside or outside an acceptable range defined by upper and lower threshold levels indicating an already faulty lead. Nor would the skilled person have found an indication as to the claimed solution in documents D3 to D5, none of which was concerned with lead impedance measurements and in particular the determination of lead anomalies or degradation.

D4 referred to a pacemaker system in which the minute volume was determined as an operating parameter for setting the pacing rate from measurements of the blood impedance. More specifically, the stand-by pacing rate was determined from a long-term average of the measured values of the minute volume in order to accommodate the system to long-term variations caused for instance by

changes in the body chemistry or a re-positioning of the electrodes. However, such causes would not have any significant effect on the value of the lead impedance as such.

The other documents were still further away from the teaching of the patent. D3 concerned an extra-corporal pacemaker function analyser detecting failures in the pacemaker's functions from a continuous sensing and processing of electrical potentials appearing on the body surface. According to D5, time intervals between detected heart beats were measured and compared *inter alia* with a running average threshold in order to establish a condition of tachycardia (abnormally high rate of heart beats). The running average threshold was obtained from a fixed number of preceding non-tachy beats.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is therefore admissible.
2. In view of the facts that, in the oral proceedings, the appellant no longer argued its case with respect to the ground of Article 100(b) EPC and that the Board is satisfied that the patent meets the requirements of Article 83 EPC, the sole issue remaining to be considered is that of inventive step (Articles 52(1) and 56 EPC).
 - 2.1 The closest prior art is given by document D1 (cf. in particular Figures 2 and 3; page 6, lines 8 to 13;

page 8, line 36 to page 10, line 8; page 12, lines 7 to 15; page 13, line 10 to page 14, line 37). It shows a lead impedance scanning apparatus for use in a pacemaker and a method of discovering defective leads in accordance with the wording of the respective preambles of patent claims 1 and 13. The impedance of stimulation leads is measured as a voltage drop at a resistor R1 connected in series with a capacitor C3, the voltage drop occurring when the capacitor delivers a pacing pulse. The voltage at R1 is compared to the voltage drops at reference resistors R2 and R2' establishing reference values serving as a high level threshold and a low level threshold, respectively. The threshold levels are preselected by properly setting the resistance of the variable resistors R2 and R2'. There is no indication that during operation of the pacemaker these threshold levels should be changed. When deviations from the preset range of acceptable impedance values are detected, another stimulation circuit, which is placed in the patient's chest, is activated so that the patient will perceive that something is wrong with the pacemaker.

A similar apparatus and method are known from Document D2 (cf. in particular Figures 2 and 3A to 3C; page 6, line 27 to page 7, line 2), according to which the impedance of a stimulation lead is measured by measuring the charging time of the output capacitor providing the pacing pulses. First and second time limits are established as reference values which serve as a high level threshold and a low level threshold, respectively. When impedance measurements exceed the threshold levels, a second, redundant lead is substituted for the defective one. Again there is no indication as to any modification of these threshold

levels acting as threshold levels during operation of the pacemaker.

2.2 The claimed apparatus and method are distinguished from the prior art according to D1 or D2 by the provision of means for developing a moving average of impedance measurements as said preselected reference and the step of developing such a moving average, respectively. The technical function of this measure is that the reference is adapted to insignificant drifts in the impedance measurements (i.e. drifts below the level of the allowable predetermined amount of deviation from the reference) which could otherwise be mistaken as a degradation of the stimulation lead.

2.3 However, such a measure is not required in a lead impedance scanning apparatus or method of discovering defective leads as known from D1 or D2.

In the operation of the known apparatus or method, the preselected reference serves as an upper and lower threshold level for determining the extreme situation of a failure of the stimulation lead, wherein any crossing of the threshold levels is indicative of either a short circuit or a broken lead and thus of a total lead failure which requires immediate action to be taken. For such a type of reference which is set at "relatively high" or "relatively low" levels with respect to the nominal value of the impedance measurement (cf. page 9, lines 1 to 7 in D1), there is no need to adapt the threshold levels to small drifts in the impedance measurements so that such a measure would not have any meaningful technical function. On the contrary, it would be apparent for a skilled person that varying the threshold levels in the operation of

the known apparatus and method would imply the risk for a potentially catastrophic defect of the lead to be detected too late. Hence, when working with the known apparatus or method, there is no conceivable incentive which would have led a skilled person to contemplate developing a moving average for the preselected reference.

- 2.4 For these reasons, the Board does not share the appellant's view that the objective problem was merely to be seen in the desire to adapt the preselected reference to drift effects in the impedance measurements.

On the other hand, a technical function of a moving average reference in the context of the claimed subject-matter becomes apparent from the statement of the problem given in column 5, lines 48 to 55 of the patent description, according to which *"not only are permanent lead abnormalities, such as insulation breakdown, lead breaks and the like, detected by arrangements in accordance with the present invention, but so also are lead impedance anomalies of a temporary or intermittent nature as well as significant but gradual variations in lead impedance which may be symptomatic of impending lead failure"*. The subject-matter of patent claims 1 and 13 addresses this specific problem if it is assumed that the preselected reference is not set to constitute a threshold for the detection of catastrophic failures, as in the prior art, but is chosen closer to the nominal impedance measurement so that a record can be kept of deviations from the norm which are above a predetermined amount but still substantially lower than deviations indicative of a total lead failure. In this manner,

temporary or intermittent anomalies may be distinguished from a gradual but significant deterioration of the stimulating lead and an impending lead failure can be detected much earlier than is possible in the prior art.

2.5 On the basis of the foregoing interpretation of the claimed subject-matter (which, in the light of the patent specification, is the only technically reasonable interpretation), and in view of the specific circumstances of the present case, in which the skilled person starting from the closest prior art would not be confronted with the more general problem suggested by the appellant, the Board accepts the problem stated in the patent specification to constitute the objective problem that is associated with the aforementioned difference and solved by claims 1 and 13 as granted.

2.6 This problem is not known from D1 or D2, nor would it have occurred to the skilled person from this prior art teaching.

Moreover, even knowledge of the teachings of documents D4 and D5, none of which is concerned with the detection of component failures, would not have motivated the skilled person to abandon in an apparatus and method according to D1 and D2 the idea of fixed threshold levels for the detection of a total lead failure.

The teaching of D4 is concerned with determining the standby pacing rate of a metabolic-demand pacemaker and based on the observation that the measured value of the minute volume (being a detectable parameter indicative of the required standby rate) shows long-term

variations which are for instance due to changes in an electrode position or in the conductivity of the blood although the real minute volume has not changed. It is the desire to compensate for these artificial changes in the measurements which has led to the idea of developing a long-term moving average of the measured minute value as a basis of reference. In contrast thereto, the lead impedance measurements according to D1 and D2 do not suffer from comparable measurement artifacts. Even long-term drifts in the detection circuit which could be due to changes in the physiological condition of the paced tissue or in the properties of electronic circuit components would have caused only minor and insignificant changes in the measured lead impedance compared to the nominal lead impedance in the order of 500 ohms and to the threshold levels (being chosen as 2000 ohms and 50 ohms in a specific example according to D1).

Similar considerations apply for the teaching of D5 (cf. in particular the abstract; claim 1; Figure 3; column 3, lines 51 to 63; column 4, lines 25 to 33; column 5, line 50 to column 6, line 5) which is concerned with the detection of tachyarrhythmia, i.e. an abnormally high rate of heart beats. In order to reliably establish a condition of tachycardia, measurements of the time intervals between successive heart beats are performed and the observed time intervals are compared with a fixed predetermined threshold as well as a four period running average threshold developed from the preceding non-tachy beats, the latter being a necessity because of the normal variability of the time intervals between non-tachy beats.

Thus, although the idea of developing a moving average of a reference for a measured parameter is known as such in the context of implantable stimulation devices from each of documents D4 and D5, it is used in a different context for solving a different problem and would not be applicable to the concept of threshold levels for the detection of a total lead failure according to D1 or D2.

Finally, the Board considers document D3 relating to an extra-corporal pacemaker function analyser which monitors electrical signals taken from a patient's body to be irrelevant for the subject-matter of the independent patent claims, in view of the fact that this document is neither concerned with impedance measurements of the stimulation leads nor with modifications to reference values for any sensed parameter.

- 2.7 Hence, in the circumstances of the present case, the skilled person would not have found in the prior art any motivation for modifying an apparatus and method according to D1 or D2 by developing a moving average of impedance measurements for the reference with a view to detecting intermittent and significant but gradual changes in the lead impedance before the occurrence of a total lead failure.

Consequently, the Board is satisfied that the subject-matter of claims 1 and 13 as granted complies with the requirements of Articles 52(1) and 56 EPC having regard to inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

R. Schumacher

G. Davies