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**D E C I S I O N**  
**of 7 June 2001**

**Case Number:** T 0416/96 - 3.4.1

**Application Number:** 86116672.6

**Publication Number:** 0236562

**IPC:** A61N1/368

**Language of the proceedings:** EN

**Title of invention:**

Apparatus for cardiac pacing with detection of cardiac evoked potentials

**Patentee:**

TELECTRONICS N.V.

**Opponent:**

BIOTRONIK Mess- und Therapiegeräte GmbH & Co Ingenieurbüro  
Berlin

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 100(a), 54, 56, 100(c), 123(2),(3)

**Keyword:**

"Article 102(3) EPC: Maintenance in amended form"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 0416/96 - 3.4.1

**D E C I S I O N**  
**of the Technical Board of Appeal 3.4.1**  
**of 7 June 2001**

**Appellant:** BIOTRONIK  
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**Representative:** Eisenführ, Speiser & Partner  
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**Respondent:** TELELECTRONICS N.V.  
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**Representative:** Kuhnen & Wacker  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 28 December 1995  
rejecting the opposition filed against European  
patent No. 0 236 562 pursuant to Article 102(2)  
EPC.

**Composition of the Board:**

**Chairman:** G. Assi (Rapporteur)  
**Members:** M. G. L. Rognoni  
B. J. Schachenmann

## Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 26 February 1996, against the decision of the Opposition Division, dispatched on 28 December 1995, rejecting the opposition against the European patent No. 0 236 562 (application number 86116672.6). The fee for appeal was paid on the same day. The statement setting out the grounds of appeal was received on 25 April 1996.

II. Opposition was filed against the patent as a whole and was based on Article 100(a) EPC, in particular on the grounds that the subject-matter of the patent was not patentable within the terms of Articles 52(1) and 56 EPC.

The Opposition Division held that the grounds of the opposition did not prejudice the maintenance of the patent as granted, having regard *inter alia* to the following documents:

(D1) US-A-4 387 717 and

(D2) US-A-4 549 548.

III. Oral proceedings were held on 7 June 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:

**Claims:**

No. 1 filed, as auxiliary request, with the letter of  
12 September 1996,  
Nos. 2 to 9 of the granted patent,  
Nos. 10, 11 filed with the letter of 7 May 2001,

**Description:**

pages 2 to 4 with insert A on page 2 filed at the oral  
proceedings on 7 June 2001,  
pages 5 to 8 of the granted patent,

**Drawings:**

sheets 1/8 to 8/8 of the granted patent.

V. The wording of claim 1 reads as follows:

*"1. An apparatus for cardiac pacing and sensing,  
comprising:  
a cardiac pacing lead (14; 14a; 80) having a first  
electrode (16; 16a; 82) on its distal end and said lead  
having a second electrode (18; 18a; 84) spaced from  
said first electrode (16; 16a; 82);  
said cardiac pacing lead (14; 14a; 80) being adapted  
for being positioned within a heart chamber;  
means (12; 12a) for transmitting and emitting an  
electrical stimulus pulse (30) to and from,  
respectively, said first electrode (16; 16a; 82) in  
unipolar mode to stimulate muscular contraction of a  
portion of said heart;  
sensing means (52, 54) coupled to said second electrode  
(18; 18a; 84), for detecting in unipolar mode during a  
predetermined window of time (36) subsequent to said  
emitting of said pulse of electrical potential used as  
said stimulus pulse (30), an electric potential*

*response (38) evoked by said stimulus pulse (30), indicating said muscular contraction; circuit means permitting said first electrode (16; 16a; 82) and said second electrode (18; 18a; 84) to be free of electrical connection between each other while transmitting said pulse and while sensing, whereby signal interference caused by residual polarization of said first electrode (16; 16a; 82) is suppressed; means (44; 46) for sensing, in bipolar mode using said first and second electrodes (16; 16a; 82; 18; 18a; 84), electrical signals indicating natural heart contraction, prior to emitting from said first electrode (16; 16a; 82), said stimulus pulse (30); means for inhibiting said transmitting means upon sensing of said heart electrical activity; and whereby at a predetermined interval before said electrical stimulus (30) is emitted and while the evoked response sensing circuit is not operating, said means for sensing electrical signals is activated and emission of said electrical stimulus (30) is inhibited upon sensing of said heart electrical activity."*

Claims 2 to 11 are dependent.

VI. The appellant's arguments may be summarised as follows.

Document D2 was considered to represent the closest state of the art. It was concerned with a pacemaker system which offered the possibility of switching between unipolar and bipolar forms of operation, depending on the choice made by a physician. The apparatus according to claim 1 differed from the system known from D2 (see Figure 1A) only in that the evoked response was sensed by a second electrode different

from the pacing electrode.

Document D1 disclosed a demand pacemaker including a first electrode for unipolar pacing and a second electrode for unipolar sensing of the electrocardiogram. Though D1 did not distinguish between the intrinsic and the evoked responses, the evoked and intrinsic cardiac signals could be sensed in the same way and, thus, the electrode 1 of the pacemaker according to D1, Figure 1, was also suitable for sensing the evoked response. As to the arrangement of the electrodes, D1 taught to space the sensing and the pacing electrodes from one another in order to minimize interference from the pacing stimulus and after potentials. The patent in suit also addressed the problem of reducing the influence of after potentials, which were due to the polarization decay on the pacing electrode resulting from the stimulus itself.

Starting from the system according to Figure 1A of D2, the skilled person at the priority date of the present invention was aware of the disadvantage of sensing the evoked response with the same electrode used for pacing. D1 offered a solution to this problem, which consisted in the provision of a sensing electrode separated from the pacing one. Thus, it was obvious to modify the switch 40 (cf. Figure 1A of D2) so that the second electrode 42 had the same function of unipolar sensing of the evoked response as electrode 1 according to D1, Figure 1. In this way, the skilled person would arrive at the apparatus of claim 1 without involving any inventive activity.

VII. The respondent's arguments may be summarised as follows.

The present invention concerned a pacing system which functioned during its cycle in both a unipolar and a bipolar mode. The choice of the mode of operation depending upon the particular time during the pacing cycle was essential for generating the stimulus as well as sensing the response in an optimum manner.

D2, contrary to the present invention as specified in claim 1, taught to sense the evoked response with the same electrode used for pacing.

D1 disclosed a demand pacemaker comprising an electrode for sensing the complete electrocardiogram and a separate pacing electrode. This document taught away from the invention because it expressly stated that the sensing electrode did not detect after potentials and, thus, could not sense the evoked responses buried in after potentials. The fact that the sensing electrode in D1 was used for intrinsic cardiac signals, whereas in the present invention the second electrode sensed the evoked response, should not be regarded as a trivial difference because intrinsic and evoked signals had different morphologies, occurred at different times and different locations.

In view of the different disclosures and teachings of D2 and D1, their combination was based on hindsight.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Amendments*

The appellant has not raised any objection based on Articles 100(c) and 123(3) EPC in opposition and appeal proceedings. The Board agrees that the amendments neither introduce subject-matter which extends beyond the content of the application as filed nor have the effect of extending the protection conferred.

3. *Novelty*

The appellant has not raised any objection based on Article 100(a) EPC on the ground that the subject-matter of claim 1 is not patentable within the terms of Articles 52(1) and 54 EPC, having regard to documents D1 and D2. The Board takes the same view that the claimed subject-matter is new.

4. *Inventive step*

4.1 Following the appellant's opinion, the Board considers that D2 represents the closest state of the art. This document discloses a demand pacemaker system comprising the following features:

- a cardiac pacing lead having a first electrode 41 on its distal end and a second electrode 42 spaced from the first electrode, the cardiac pacing lead being adapted for being positioned within a heart chamber (see Figures 1A and 1C),
- means 32 for transmitting and emitting an electrical stimulus pulse to and from, respectively, the first electrode 41 in unipolar mode to stimulate muscular contraction of a portion of said heart (see column 4, lines 5 to 12, column 5, lines 15 and 16, column 6, lines 8



to 11),

- sensing means 34 coupled to the first electrode 41 for detecting, in unipolar mode during a predetermined window of time subsequent to emitting of the stimulus pulse, an electric potential response evoked by the stimulus pulse, indicating muscular contraction (see column 1, lines 61 to 64, Figure 2B, blocks 263, 265, 266 for the unipolar sensing of the evoked response, and blocks 264, 268 for the time window),
- circuit means 36, 40 permitting the first electrode 41 and the second electrode 42 to be free of electrical connection between each other,
- means 34, 36, 40 for sensing, in bipolar mode using the first and the second electrodes, electrical signals indicating natural heart contraction, prior to emitting the stimulus pulse from the first electrode 41 (see column 3, line 67, to column 4, line 2, Figure 2A, blocks 207, 208, 233, 234),
- means for inhibiting the transmitting means upon sensing of the natural heart electrical activity, whereby at a predetermined interval before the electrical stimulus is emitted and while the evoked response sensing circuit is not operating, the means for sensing natural electrical signals is activated and the emission of the electrical stimulus is inhibited upon sensing of the natural heart electrical activity (see Figure 2A, block 238, the "NO" branch meaning that no stimulus is generated, according to column 5, lines 21 to 24).

Thus, the apparatus according to claim 1 differs from the pacemaker system known from D2 in that the evoked response is sensed by means of a second electrode 18 different from the pacing electrode 16 (see Figures 1 and 5 of the patent in suit), and in that the first electrode and the second electrode are free of electrical connection while the first electrode transmits the stimulus pulse and the second electrode senses the evoked response.

4.2 The provision of sensing the evoked response by means of a second electrode different from the pacing electrode and of making the electrodes free of electrical connection is considered to represent the solution to the problem, disclosed in the granted patent, column 2, lines 2 to 8 and 55 to 58, column 9, lines 23 to 29, and Figure 2, and consisting in the fact that, when the same electrode is used for both generating a stimulus pulse and sensing the evoked response, the latter is masked by the exponential decay of the polarization of the electrode resulting from the stimulus itself.

4.3 Figure 1 of document D1 discloses a demand pacemaker comprising a sensing electrode 1 and a ventricular pacing electrode 10. According to Figure 2, the pacing electrode is situated on the distal end of the electrical lead 24 of the pacemaker, whereas the sensing electrode is in the form of cylindrical ring 26 spaced away from the tip electrode 23. The sensing electrode is connected to a QRS amplifier acting as an electrocardiogram amplifier (see column 2, lines 54 to 57). Since the QRS amplifier is electrically connected to the pacemaker metallic case 4 which has the function of an indifferent electrode (see column 2, lines 57 to

61), sensing of the electrocardiogram is unipolar. Moreover, the pulse generator is electrically grounded to the case 4 (see column 2, lines 66 to 68), which means that pacing is also unipolar. As regards the arrangement of the electrodes, D1, column 2, lines 1 to 4, states that the "*sensing electrode is carefully separated from the pacing electrode to minimize cross-coupling interference from the pacing pulses and after potentials*", this statement being repeated on column 3, lines 23 to 26. The appellant argues that the expression "*after potentials*" refers to the physical phenomenon of the exponential decay of the polarization of the pacing electrode resulting from the emitted stimulus. Considering that this statement, which is not disputed by the respondent, reflects a plausible interpretation, the Board takes the view that, in the light of D1, the problem of avoiding interference between pacing pulses and sensed cardiac electrical activity was, at the priority date of the present invention, known in the art.

- 4.4 According to D1, column 1, lines 11 to 21, prior art demand pacemakers are controlled by sensing the electrocardiogram und using it to determine whether the pacing stimulus is required to sustain normal cardiac rate. In a unipolar system, the electrocardiogram is sensed by means of the same electrode that is used for pacing the heart. However, for pacing, it is desirable to minimize the electrode surface, whereas, for sensing, the size of the electrode should be maximized (see column 1, lines 21 to 27). Thus, electrode design in a unipolar system is a matter of compromising size to achieve a balance suitable for both adequate pacing and sensing (see column 1, lines 27 to 30). According to D1, it is possible to overcome the size compromise

problem and achieve improved sensing by using separate pacing and sensing electrodes (see column 1, lines 32 to 48, lines 61 to 68, column 2, lines 1 to 6). Furthermore, it is pointed out in D1 that the particular arrangement of the pacing and sensing electrodes carefully separated from one another permits sensing of the electrocardiogram without undue interference from the pacing pulses and after potentials. D1, however, does not distinguish between intrinsic and evoked responses.

4.5 Following the problem and solution approach for assessing inventive step, the skilled person starts from the pacemaker system known from D2, in which the evoked response is sensed in unipolar mode with the same electrode used for pacing. The skilled person knows from D1 that sensing cardiac activity with the pacing electrode has the disadvantage that the response is masked by the exponential decay of the polarization resulting from the stimulus itself. The question thus arises, whether the skilled person, with the aim of avoiding this disadvantage, would consider to modify the pacemaker system of D2, as far as the sensing of the evoked response is concerned, according to the teaching of D1, which discloses using a sensing electrode separated from the pacing one for detecting all cardiac signals.

4.6 For the combination of two prior art documents to be justified, it is essential, in the Board's judgement, that there is a link between the documents and that the skilled person, while combining them, does not depart from the essential teaching of the closest document in order to have the possibility of including the features disclosed in the other document. In the present case,

both documents D1 and D2 are in the common field of demand pacemakers. However, the combination would be based on an *ex post facto* analysis, if essential structural or functional features of the pacemaker of D2 had to be considerably modified for achieving the functional arrangement of the electrodes as shown in D1. Therefore, the essential teaching of D2 needs to be considered.

Document D2 is essentially concerned with the problem of providing a pacemaker which can automatically switch between unipolar and bipolar forms of operation, the switching being programmed for optimal operation. Thus, D2 (see Figure 1A and 1C, column 2, line 61, to column 3, line 9) discloses a pacemaker system comprising means 32 for delivering stimulus pulses, means 34 for sensing heart signals, an electrode configuration 41, 42, 43, and controllable means 36, 40 for switching the electrodes so as to provide selection between unipolar and bipolar operation for optimizing the electrode configuration for predetermined pacing events. In particular, the electronically controlled switch 40 operates to switch either the second ring electrode 42 or the indifferent electrode 43 on the pacemaker casing to the system ground (see column 3, lines 64 to 67). A bipolar operation is achieved, when the switch 40 connects the second electrode 42 to the system ground (see column 3, line 67, to column 4, line 5), whereas a unipolar operation is obtained, when the switch 40 connects the indifferent electrode 43 to the system ground, the second electrode 42 being then not connected to the pacemaker (see column 4, lines 5 to 9).

4.7 According to the appellant, the combination of document

D1 with D2 would require an obvious modification of the switching means 40 producing the result that the electrode 42, not 41, has the function of sensing the evoked response in unipolar mode. In the Board's opinion, however, such a modification would involve a departure from an essential teaching of D2, which consists in using the tip electrode 41 as the sensing electrode for both the evoked response and the intrinsic response, and in connecting the ring electrode 42 to ground in bipolar sensing or letting it float in unipolar sensing. It is remarked that, at the oral proceedings, the appellant's representative indeed agreed with the argument that the combination under discussion should not deform the teaching of D2, because he underlined the fact that both D1 and D2 disclose pacemakers with only one pacing electrode and one sensing electrode, on which basis he excluded a combination entailing the introduction in the pacemaker of D2 of a third electrode, besides electrodes 41 and 42, for sensing the evoked response in unipolar mode, without any modification of the switching means 40.

- 4.8 In his arguments, the appellant presumes that the sensing electrode of the pacemaker of D1 is suitable for sensing the evoked responses, although D1 does not distinguish, at least explicitly, between intrinsic and evoked signals. The Board does not deny the possibility that the electrocardiogram detected by the sensing electrode includes both signals. However, following the respondent's opinion, this fact should not be interpreted as meaning that D1 indeed teaches to provide a sensing electrode suitable for sensing the evoked response. In this respect, the respondent has underlined that intrinsic and evoked signals are substantially different as regards their morphologies,

time and locations of occurrence, which differences would imply different requirements for sensing. The appellant, who carries the burden of proof for this fact, has not provided any evidence undermining the respondent's view. The Board considers this a further argument against the combination of D1 and D2.

4.9 Summarizing, the sensing in D2 and D1 is performed according to two substantially different principles. In D2, the active tip electrode 41 is used for sensing all cardiac intrinsic or evoked responses, whereas the ring electrode 42 represents the indifferent electrode in the bipolar sensing of the intrinsic response. In D1, an electrode spaced from the tip electrode is used as active sensing electrode for all cardiac signals, whereby the pacemaker casing is the indifferent electrode. According to the present invention, both electrodes can be used as active electrodes.

The point is not whether the skilled person could have arrived at the invention by modifying the prior art, but rather whether, in the light of the technical problem addressed, he or she would have done so in view of the promptings in the prior art. The Board is not convinced that the skilled person would indeed have made the combination of documents D1 and D2. The combination of D1 and D2 could only lead to the claimed apparatus if features are combined, which are selected from the teachings of both documents having knowledge of the invention. Making such a selection entails hindsight. When a doubt exists while assessing inventive step in opposition appeal proceedings, the benefit of the doubt should be given to the proprietor of the patent.

5. For these reasons, taking into consideration the amendments made, the Board comes to the conclusion that the patent as amended according to the respondent's request meets the requirements of the EPC.

## **Order**

### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain the patent as amended in the following version:

#### **Claims:**

No. 1 filed, as auxiliary request, with the letter of 12 September 1996,

Nos. 2 to 9 of the granted patent,

Nos. 10, 11 filed with the letter of 7 May 2001,

#### **Description:**

pages 2 to 4 with insert A on page 2 filed at the oral proceedings on 7 June 2001,

pages 5 to 8 of the granted patent,



**Drawings:**

sheets 1/8 to 8/8 of the granted patent.

The Registrar:

The Chairman:

R. Schumacher

G. Assi