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D E C I S I O N
of 22 March 2005

Case Number: T 0524/03 - 3.4.1

Application Number: 93107473.6

Publication Number: 0571797

IPC: A61N 1/05

Language of the proceedings: EN

Title of invention:
Heart stimulation apparatus

Patentee:
St. Jude Medical AB

Opponent:
Biotronik GmbH & Co. KG

Headword:
-

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

Keyword:
"Inventive step - no (main request)"
"Added subject-matter - no (auxiliary request)"
"Lack of clarity - no (auxiliary request)"
"Inventive step - yes (auxiliary request)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0524/03 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 22 March 2005

Appellant: (Opponent)
Biotronik GmbH & Co. KG
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Respondent: (Proprietor of the patent)
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Representative:
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 4 March 2003 rejecting the opposition filed against European patent No. 0571797 pursuant to Article 102(2) EPC.

Composition of the Board:

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

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 6 May 2003, against the decision of the opposition division, dispatched on 4 March 2003, rejecting the opposition against the European patent No. 0 571 797. The fee for the appeal was paid on 6 May 2003 and the statement of the grounds of appeal was received on 7 July 2003.

II. The opposition had been filed against the patent as a whole based on Article 100(a) EPC and concerned, in particular, objections under Articles 52(1), 54 and 56 EPC.

III. In the decision under appeal, the opposition division held, *inter alia*, that the subject-matter of claim 1 of the patent as granted involved an inventive step, having regard in particular to the following prior art documents:

D2: US-A-4 628 934 ("Anlage 2")
D3: US-A-4 848 352 ("Anlage 3").

IV. With the statement of grounds of appeal, the appellant submitted the following document:

D6: US-A-4 958 632.

V. Oral proceedings were held on 22 March 2002.

VI. The appellant requested that the decision under appeal be set aside and the patent be revoked.

Furthermore, the appellant requested that document D6 be admitted into the proceedings.

VII. The respondent (patentee) requested that the appeal be dismissed and the patent be maintained as granted (main request), or that the patent be maintained on the basis of the following documents (auxiliary request):

Claims: No. 1 to 9 filed in the oral proceedings on 22 March 2002;

Description: columns 1 to 9 filed in the oral proceedings;

Figures: No. 1 to 3 filed in the oral proceedings;
No. 4 to 6 of the patent as granted.

Furthermore, the respondent requested that the late-filed document D6 be disregarded.

VIII. The wording of Claim 1 according to the respondent's main request reads as follows:

"1. A heart stimulating apparatus for intracardial stimulation of heart tissue and/or sensing heart signals comprising an electrode device with an electrode head installed on the distal end thereof, whereby the electrode head is equipped with a first conductive surface (4 - 7, 231, 232, 304, 305, 318, 319) for stimulating heart tissue and/or sensing heart signals connected to a first conductor (9 - 12, 233, 234, 306, 307, 320, 321) and at least a second conductive surface (4 - 7, 231, 232, 304, 305, 318,

319) for stimulating heart tissue and/or sensing heart signals, said second conductive surface (4 - 7, 231, 232, 304, 305, 318, 319) is insulated from the first conductive surface (4 -7, 231, 232, 304, 305, 318, 319) and connected to a second conductor (9 - 12, 233, 234, 306, 307, 320, 321), insulated from the first conductor (9 - 12, 233, 234, 306, 307, 320, 321), a stimulation pulse generator (21, 221) and a detector (22, 222) and a switch (15, 237) for connecting one of said conductive surfaces (4 - 7, 231, 232, 304, 305, 318, 319), or a plurality of said conductive surfaces (4 - 7, 231, 232, 304, 305, 318, 319), to the stimulation pulse generator (21, 221) and/or the detector (22, 222) in any desired manner, wherein the switch is controlled with the aid of an autocapture means in such a way that the conductive surfaces (4 - 7, 231, 232, 304, 305, 318, 319) are automatically connected in a plurality of different combinations, via the conductors (9 - 12, 233, 234, 306, 307, 320, 321), to the stimulation pulse generator (21, 221) and tested for stimulation and/or sensing level characterised in that a predetermined number of said combinations are selected which have the best stimulation and/or sensing level, and then the selected combinations are tested in order to achieve the optimal stimulation with minimal energy consumption and/or to achieve an optimal sensing level."

Claims 2 to 17 are dependent on claim 1.

The wording of claim 1 according to the respondent's auxiliary request reads as follows:

"1. A heart stimulating apparatus for intracardial stimulation of heart tissue and/or sensing heart

signals comprising an electrode device with an electrode head installed on the distal end thereof, whereby the electrode head is equipped with a plurality of conductive surfaces including a first conductive surface (4 - 7) for stimulating heart tissue and/or sensing heart signals connected to a first conductor (9 - 12) and at least second and subsequent conductive surfaces (4 - 7) for stimulating heart tissue and/or sensing heart signals, said second and subsequent conductive surfaces (4 - 7) being insulated from the other conductive surfaces (4 - 7) and each connected to a further conductor (9 - 12), insulated from the other conductors (9 - 12), a stimulation pulse generator (21) and a detector (22) and a switch (15) for connecting one of said conductive surfaces (4 - 7), or a plurality of said conductive surfaces (4 – 7), to the stimulation pulse generator (21) and/or the detector (22) in any desired manner, wherein the switch is controlled with the aid of an autocapture means in such a way that the conductive surfaces (4 - 7) are automatically connected in a plurality of different combinations from among all possible combinations, via the conductors (9 - 12), to the stimulation pulse generator (21) and automatically tested according to a first test for stimulation threshold or sensing level wherein said apparatus further comprises means for automatically selecting a predetermined number of said combinations which have the best stimulation threshold or sensing level, said means then automatically testing the selected combinations according to a second test in order to achieve the optimal stimulation with minimal energy consumption or to achieve an optimal sensing level, whereby said second test of said selected combinations

is routinely performed to thereby ensure that it is the combination having the optimal threshold which is permanently activated."

Claims 2 to 9 are dependant on claim 1.

IX. The appellant's submissions may be summarised as follows:

The preamble of claim 1 according to the respondent's main request related to a heart stimulating apparatus comprising switching means for automatically connecting different electrode combinations to the stimulation pulse generator, as disclosed in document D2. The procedure for selecting an optimal electrode combination for stimulation and/or sensing specified in the characterising portion of the claim was known from the prior art (see for instance D6). Moreover, it corresponded to what the physician would do when programming a pacemaker for a particular patient. Thus, the subject-matter of claim 1 according to the main request did not involve an inventive step within the meaning of Article 56 EPC.

Claim 1 according to the auxiliary request was not admissible under Article 123(2) EPC because the alternative embodiment relating to the selection of electrode configurations on the basis of the sensing level found no support in the application as originally filed.

Furthermore, claim 1 of the auxiliary request was not limited to an apparatus which selected a subset of electrode combinations according to a first test and

then, at regular intervals and independently of the first test, performed a second test on the selected combinations. On the contrary, the claim covered also an apparatus which arrived at the best electrode combination for a particular patient on the basis of a standard selection procedure performed in two stages, or an apparatus which routinely monitored an active electrode configuration in order to detect a lead failure and replace it when such failure occurred (cf. D6). As it was obvious to apply such electrode selection or electrode monitoring procedures to the apparatus known from D2, the subject-matter of claim 1 according to the auxiliary request did not involve an inventive step.

X. The respondent argued essentially as follows:

Claim 1 according to the patent in suit was directed to a heart stimulating apparatus which comprised a plurality of electrode combinations and means for selecting a predetermined number of electrode combinations and for determining which one of the preselected combinations guaranteed optimal stimulation with minimum energy consumption and/or optimal sensing level. The reference in the preamble of the claim to switch means controlled with the aid of an autocapture means and to conductive surfaces being automatically connected in a plurality of different combinations made clear that the tests specified in the characterising portion were actually performed by the apparatus and could not be carried out by a physician. As none of the prior art documents disclosed a pacemaker which automatically arrived at the selection of the optimal electrode combination by means of the procedure

specified in the characterising portion of the claim, the subject- matter of this claim involved an inventive step.

As to the auxiliary request, the wording of claim 1 clearly specified that there were two independent tests for selecting the optimal configuration and that the first test was directed to selecting a predetermined number of electrode configurations whereas the second test was limited to testing repeatedly and routinely the electrode configurations preselected at the end of the first test in order to determine an optimal electrode configuration. This configuration was permanently activated in the sense that it replaced an electrode configuration with less-than-optimal stimulation threshold or sensing level. As none of the prior art documents suggested the provision of means for carrying out the first and second tests specified in the claim and, in particular, for performing the second test routinely in order to guarantee that the optimal electrode configuration was permanently activated, the claimed subject-matter involved an inventive step.

Reasons for the decision

1. The appeal is admissible.

Admissibility of document D6

2.1 The appellant filed D6 with the statement of the grounds of appeal because it concerned the **automatic selection** of electrodes in a pacemaker, a feature of

claim 1 which according to the contested decision was not disclosed in the previously cited prior art.

2.2 The respondent, however, requested that D6 not be admitted into the proceedings, *inter alia*, on the ground that it was not *prima facie* more relevant to the patent in suit than the documents already on file.

3.1 D6 relates to a heart stimulating apparatus with leads 17, 19 and 29 (see Figure 1), whereby lead 29 is "illustrative of a plurality of leads that may be coupled to various sites of the patient's heart in order to provide, for example, stimulation that would defeat an arrhythmia or to provide redundant leads to replace defective leads 17 or 19" (column 8, lines 3 to 7).

3.2 According to Figure 2, the pacemaker includes a microprocessor 100 and a multiplexer (*ie* a *"switch"*) 106 for receiving analogue data from a first input 138a via the first lead 19 to the patient's ventricle and a second input 138b coupled via the second lead 17 to the patient's atrium (see column 8, lines 8 to 15).

As specified in column 8, lines 45 to 50: "*It is contemplated that the microprocessor could choose which of the inputs 138 a, b, d and e that would provide the most efficient sensing of the atrial and ventricular signals, or require the least power from the power source 126, or most effectively breakup a cardiac arrhythmia*".

The control output signals of the microprocessor are applied via conduits 131 to latch drivers 134 and by

bus 132 to corresponding "select switches" 130 which provide appropriate pacemaker pulses via leads 17 and 19 (or 29) to the atrium and ventricle "*in accordance with the processes stored in the memory 102*" (cf. column 10, line 64 to column 11, line 8).

The select switches 130 are under the control of the microprocessor 100 to couple the output of the first driver 134a *"between selected of the outputs 19a, 19b, and 19c"*, whereby 19a and 19c represent two conductive surfaces of the electrode and 19b the casing of the pacemaker (see column 11, lines 19 to 28).

In addition to being able to pulse in bipolar or unipolar mode, the microprocessor responds to the detection of a faulty lead by controlling the select switches 130 so as to select a different combination of leads or of "*conductors of leads*" (*ie* conductive surfaces) to be coupled to the pulse generator (see column 11, lines 38 to 55).

Failure of one of the leads 17 or 19 can be detected by loss of capture (column 11, lines 56 to 58). *"Upon detection of such a failure, the microprocessor 100 selects a different one of the processes or programs stored within the memory 102 to apply signals to one of the selected switches 130 to cause a re-connection of the leads 19a (or 29) in a manner as illustrated above"* (see column 11, lines 64 to 68).

In column 10, lines 46 to 54, D6 also describes autocapture means as specified in the contested patent.

3.3 In summary, D6 relates to a pacemaker comprising, *inter alia*, the following features which appear to be relevant to the claimed subject-matter:

-- the electrode head comprises a first conductive surface (tip electrode) and at least a second conductive surface (ring electrode);

-- microprocessor controlled switches connect the conductive surfaces to the pulse generator (or to the sensing means) according to programs stored in a memory;

-- the correct functioning of the electrodes is monitored by verifying whether the heart is properly stimulated and, in case of failure of an electrode, a different combination of electrodes (or conductive surfaces) is selected.

3.4 D3 shows an electrode head for a pacemaker comprising a plurality of conductive surfaces (see Figure 3). In the event of malfunction, one of the electrode members may take over the function of another, failing electrode member (see column 2, lines 30 to 37).

3.5 As pointed out by the appellant, D6 goes beyond the teaching of D3 in that it refers to a pacemaker which switches from a predetermined combination of electrodes to a different predetermined combination in the event of malfunction detected, for example, by a failure to capture the heart.

Thus, the admission of the late-filed document D6 into the appeal proceedings is justified.

Respondent's main request

4.1 D2 (see Figures 1 and 3) shows a heart stimulating apparatus for intracardial stimulation of the heart tissue and/or sensing heart signals comprising the following features recited in the preamble of claim 1:

-- an electrode device with an electrode head (26, 28) installed on the distal end thereof, whereby the electrode head is equipped with a first conductive surface (31 - 34) for stimulating heart tissue and/or sensing heart signals connected to a first conductor (65 - 68) and at least a second conductive surface (31 - 34) for stimulating heart tissue and/or sensing heart signals, said second conductive surface is insulated from the first conductive surface and connected to a second conductor (65 - 68);

-- a stimulation pulse generator and a detector (see Figure 3 "*pacer electronics*");

-- and a switch (70) for connecting one of said conductive surfaces, or a plurality of said conductive surfaces, to the stimulation pulse generator and/or the detector in any desired manner.

4.2 Furthermore, document D2 specifies the following:

-- *"in accordance with the teachings of the present invention, selection may be made either by programming an electronic switching/selection*

circuit external to the pacer case by a pacer programmer and/or selection may be made by dynamically switching the electronic electrode switching/selection circuit on a sampling basis by the pacer control electronics. The selection signal may, in the first desired instance, originate in the main pacer programming circuit or the selection circuit may itself be capable of directly receiving programming signals from a programmer." (column 4, lines 41 to 51);

-- *"in accordance with established procedures, electrodes 31 - 34 in each of the tip electrode assemblies 26 and 28 are tested, as for threshold, whereby the physician may make a determination as to which of the various electrodes 31 - 34 will be used for which of various pacer functions"* (column 6, lines 3 to 8).

The fact that in D2 the switching of electrode configurations can be effected automatically by the pacer and that a test of the electrode configurations is carried out on the basis of the stimulation threshold, for which it is implicit to use autocapture means, implies that the apparatus of D2 also comprises the following features recited in the preamble of claim 1:

-- the switch (70) is controlled with the aid of an autocapture means in such a way that the conductive surfaces are automatically connected in a plurality of different combinations via the conductors (65 - 68), to the stimulation pulse

generator and tested for stimulation and/or sensing level.

In conclusion, D2 undisputedly discloses all the features recited in the preamble of claim 1.

5.1 According to the appellant, the first feature of the characterising part of claim 1 *("a predetermined number of said combinations are selected which have the best stimulation and/or sensing level")* would also be known from document D2 because this document referred to the selection of suitable electrode configurations made by the physician (cf D2, column 6, lines 3 to 8) and claim 1 allowed this feature to be interpreted accordingly. Thus, in the appellant's opinion, the claimed subject-matter differed from the apparatus shown in D2 only in that:

"the selected combinations are tested in order to achieve the optimal stimulation with minimal energy consumption and/or two achieve an optimal sensing level."

This testing procedure, however corresponded to the standard selection of the most suitable electrode configuration for stimulation and/or sensing which was normally performed during the setting and programming of a pacemaker, or which could be initiated by the detection of a lead failure (cf D6, column 11, lines 56 to 68). It did not refer to a separate test routine carried out independently of the initial selection of viable electrode configurations. Thus, a skilled person wishing to implement a pacemaker according to the teaching of D2 would have necessarily arrived at a

device falling within the terms of claim 1 of the contested patent.

5.2 In the respondent's view, however, D2 did not disclose or suggest performing automatically a first test to select a predetermined number of electrode combinations and a second test on the selected predetermined number of electrode configurations to find the most satisfactory configuration for stimulation or sensing purposes. D2 merely implied that the selected electrode should be monitored for correct function and did not teach how a substitution should be decided.

6.1 The Board agrees with the appellant that the test procedures specified in the characterising portion of the claim do not necessarily define two separate tests, as indicated in the flow charts of Figures 5 and 6 of the patent in suit. The claim could also be interpreted as specifying a two-stage selection procedure for determining the electrode combination best suited to a particular patient. Such procedure does not necessarily consist of two independent tests to be carried out automatically, but it could be performed by the physician during the initial setting of the pacemaker. In particular, the wording *"the conductive surfaces are automatically connected in a plurality of different combinations"* may simply relate to the fact that the switch is programmed to connect certain electrode surfaces to the pacemaker's output, as taught in D2, and does not imply that the selection of a predetermined number of electrode combinations with the lowest stimulation thresholds should be performed "*automatically*", i.e. without the intervention of the physician.

Furthermore, there is no indication in the claim that the test directed to the final selection of the electrode configuration to be activated should be performed repeatedly and independently of an initial selection of electrode configurations suitable for stimulation or sensing.

6.2 The Board considers that it would have been obvious to a person skilled in the art, wishing to programme the device known from D2 for a particular patient, to select among all the possible electrode configurations a number of combinations which met some standard criteria for stimulation threshold and sensing level and then to test the selected combinations in order to find the most suitable one for the patient. In doing so, the skilled person would have arrived at a pacemaker falling within the terms of claim 1 of the contested patent.

6.3 For the sake of completeness, the Board wishes to point out that the wording of claim 1 also covers a device as known from D2 but with only first and second conductive surfaces and the casing as indifferent electrode. In the language of the claim, the programming of such a device would be carried out as follows:

-- the predetermined number (two) of electrode combinations consisting of the tip and ring electrode (for bipolar stimulation) and of the tip electrode and the casing (for unipolar stimulation) which have the best stimulation threshold are selected;

Once these two combinations have been programmed into the pacemaker, the physician would wish to determine, for instance on the basis of energy requirements for proper stimulation, which of the two combinations would be suitable for a particular patient. Thus, it would be obvious to the skilled person to make provision for:

-- testing the selected combinations in order to achieve optimal stimulation with minimal energy consumption.

Furthermore, it would be obvious to provide such an apparatus with means for testing the proper functioning of the active electrode combination and for switching to an alternative viable combination in order to guarantee optimal stimulation, as taught in D6, column 11, lines 56 to 68.

6.4 In summary, the Board finds that the subject-matter of claim 1 according to the respondent's main request does not involve an inventive step within the meaning of Article 56 EPC.

Respondent's auxiliary request

7.1 Claim 1 according to the auxiliary request differs from the independent claim of the main request essentially in that it is directed to a heart stimulating apparatus which can perform the selection of electrode configurations with respect to stimulation threshold **or** sensing level, and in that it further specifies the following features:

-- the electrode head is equipped with a *"plurality of conductive surfaces including a"* first conductive surface and at least *"second and subsequent conductive surfaces"* for stimulating heart tissue and/or sensing heart signals;

-- the conductive surfaces are "*automatically*" tested *"according to a first test for stimulation threshold"* or sensing level "*wherein said apparatus further comprises means for automatically selecting*" a predetermined number of said combinations which have the best stimulation threshold or sensing level;

-- *"said means then automatically test the selected combinations according to a second test";*

-- "*whereby said second test of said selected combinations is routinely performed to thereby ensure that it is the combination having the optimal threshold which is permanently activated".*

In other words, claim 1 according to the auxiliary request specifies that the electrode head is equipped with a plurality of conductive surfaces and that the apparatus comprises means for carrying out a first test for automatically selecting a predetermined number of electric combinations which have the best stimulation or sensing level, and for carrying out a second test on the selected electric combinations, whereby the second test is routinely performed to ensure that the combination with the optimal stimulation threshold is actually selected for use.

7.2 According to the appellant, the alternative covered by the claim and relating to the sensing level would not be supported by the original disclosure. In fact, the claimed apparatus was essentially based on the flow charts of Figure 5 and 6, as far as a test for stimulation threshold was concerned. However, the original application documents did not contain any specific reference to the effect that the same tests should be applied for the determination of the sensing level.

7.3 The Board agrees with the appellant that the original disclosure does not provide a detailed description of a test for determining the sensing level of an electrode combination. However, as pointed out by the respondent, the originally filed description (see page 9, lines 24 to 26) specifies that "*analogously the autocapture function unit may select a combination of conductive surfaces 4, 5, 6, 7 which provides the best sensing level for the detector 22*". This statement following the description of the flow charts of Figure 5 and 6 clearly points to the possibility of using the same test procedure and the same autocapture function for selecting electrode combinations suitable for stimulation or for sensing. Furthermore, it is implicit to the skilled person that an autocapture function unit can provide information about not only the stimulation threshold of an electrode combination but also the sensing level of a sensing electrode, since the detection of a failure to capture may depend on the stimulation threshold or on the sensing level.

In summary, the Board considers that the alternative embodiment covered by the claim and consisting in

testing the sensitivity of electrode combinations finds support in the original application documents.

7.4 As to the admissibility of the other amendments made to the patent documents, no objections were raised by the appellant. The Board also concurs that they do not violate Articles 123(2) and (3) EPC.

8.1 As to the new claim wording, the appellant furthermore argued that the last clause of the claim ("whereby said second test of said selected combinations is routinely performed to thereby ensure that it is the combination having the optimal threshold which is permanently activated") was open to interpretation. In particular, it did not necessarily mean that the second test was repeatedly performed after completion of the first test and that the result of the second test was to ensure the activation of the optimal electrode combination.

This wording could simply mean that, every time the predetermined number of electrode combinations was selected at the end of the first test, the second test was performed on these selected electrode combinations as a matter of routine, for instance during the initial setting of the pacemaker, in order to ensure that the optimal electrode configuration was activated.

Furthermore, in the appellant's opinion, a test which was to detect and automatically replace a malfunctioning lead, as known from D6 (col. 11, lines 56 to 63) would also be covered by the wording of the claim. Thus, the straightforward application of the teaching of D6 to an apparatus according to D2 would lead the skilled person to the claimed subject-matter.

8.2 As pointed out by the respondent, the term *"routinely"* has to be interpreted in the context of the claim and of the disclosure. The claim specifies a first test which is performed automatically for selecting a predetermined combination of electrodes. The claim then specifies that the second test of the selected combinations is "*routinely*" performed in order to ensure that the combination having the optimal threshold is permanently activated. It is clear that "*routinely*" applies to the way the second test is performed. In the context of the patent in suit, there is no doubt that the second test is performed as a subroutine once the predetermined number of electrode configurations with the best stimulation threshold or sensing level has been automatically selected by the first test.

8.3 In summary, the Board has no doubt that the claim can only be interpreted as referring to means which perform a first test in order to select a predetermined number of viable electrode combinations and that a second test should be performed repeatedly ("*routinely*") in order to ensure that the optimal electrode combination is selected and actually activated.

9.1 The subject-matter of claim 1 according to the auxiliary request differs from the apparatus known from D2 essentially in that:

-- the conductive surfaces are automatically tested according to a first test for stimulation of threshold and sensing level;

and the apparatus further comprises means for:

-- automatically selecting a predetermined number of electrode combinations which have the best stimulation threshold or sensing level, and

-- then automatically testing the selected combinations according to a second test in order to achieve an optimal stimulation with minimum energy consumption or to achieve an optimal sensing level,

-- whereby said second test of said selected combinations is routinely performed to thereby ensure that it is the combination having the optimal threshold which is permanently activated.

9.2 As pointed out by the respondent, the purpose of the first test is to select among all possible electrode configurations a predetermined number of combinations that meet certain criteria as to stimulation threshold or sensing level. The second test, however, is meant to be performed routinely, *i.e.* repeatedly and on a regular basis, during the operation of the pacemaker in order to find out which of the predetermined electrode combinations offers the best stimulation threshold or sensing level, whereby the optimal electrode combination becomes the active combination.

The above features should ensure that the selection of the best electrode combination from a fairly large number of possible electrode configurations could be performed routinely without too much discomfort for the patient since the final selection is made only on the

basis of those preselected combinations which are known to ensure a certain stimulation threshold or sensing level.

9.3 The only arguments submitted by the appellant against the inventive step of the claimed subject-matter were based on an interpretation of the claimed invention which, in the Board's view, is not supported by the claim wording (see item 8.1 above).

9.4 As pointed out above, D6 relates to a pacemaker which, inter alia, comprises means for testing the functioning of the active lead by monitoring, for instance, heart activity after the pacing of the ventricle, and for automatically switching to a different electrode combination in case of lead failure. However, there is no suggestion in D6 to perform a test for determining the optimal electrode combination for stimulation or sensing and for ensuring that such a combination is actually activated. Indeed, there is no provision in D6 for replacing an active electrode with one which may have a better stimulation threshold or sensing level, unless it fails.

9.5 Hence, the Board considers that, in the light of the cited prior art and of the general knowledge common in the field of pacemakers, it would not be obvious to a person skilled in the art, starting from a pacemaker according to D2, to arrive at an apparatus falling within the terms of claim 1. The subject- matter of this claim thus involves an inventive step within the meaning of Article 56 EPC.

Claims 2 to 9 are dependent on claim 1 and therefore satisfy the requirements of Article 56 EPC.

10. In summary, the Board is satisfied that the patent documents according to the respondent's auxiliary request overcome the grounds of opposition and meet the requirements of the EPC so that the patent can be maintained on the basis thereof.

Order

For the above 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 according to the respondent's auxiliary request on the basis of the following documents:

Claims: No. 1 to 9 filed in the oral proceedings on 22 March 2005;

Description: columns 1 to 9 filed in the oral proceedings;

Figures: No. 1 to 3 filed in the oral proceedings;
No. 4 to 6 of the patent as granted.

The Registrar: The Chairman:

R. Schumacher G. Davies