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Bezeichnung der Erfindung: Body stimulator programmer
Title of invention:
Titre de l'invention :

Klassifikation / Classification / Classement : A61N 1/362

ENTSCHEIDUNG / DECISION

vom / of / du 11 September 1990

Anmelder / Applicant / Demandeur :

Patentinhaber / Proprietor of the patent /
Titulaire du brevet :

MEDTRONIC, INC.

Einsprechender / Opponent / Opposant :

BIOTRONIK Mess- und Therapiegeräte GmbH
& Co.

Stichwort / Headword / Référence :

EPÜ / EPC / CBE Article 56

Schlagwort / Keyword / Mot clé :

Main and first auxiliary requests: Inventive
Step (No);
second auxiliary request: Inventive Step
(Yes).

Leitsatz / Headnote / Sommaire



Case Number : T 165/89 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 11 September 1990

Appellant :
(Opponent)

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Decision under appeal :

Decision of the Opposition Division of the European
Patent Office dated 8 December 1988 rejecting
the opposition filed against European patent
No. 0 011 935 pursuant to Article 102(2) EPC.

Composition of the Board :

Chairman : K. Lederer

Members : H.J. Reich

L.C. Mancini

Summary of Facts and Submissions

I. European Patent 0 011 935 was granted on the basis of European patent application 79 302 451.4.

II. The Appellant filed a notice of opposition against this patent on the ground that its subject-matter did not involve an inventive step in view of the generally known state of the art in the pacemaker-field and the apparatus known from document.

D1: DE-A-2 163 482.

III. The Opposition Division rejected the opposition on the ground that the apparatus known from document D1 has no control access for the energy levels of the pacing pulses but uses an automatic threshold testing procedure, whereas in the invention the external apparatus dictates the energy level of pulses at each stage of the threshold operation. Reorganising the known apparatus accordingly and applying additionally generally known keyboards, transmitters of encoded signals, conductor means to the patient, display means for the energy level and computing means would not be suggested by the cited prior art.

IV. The Opponent lodged an appeal against this decision.

V. Based on Article 114(1) of the EPC, the Board drew, in its communication accompanying a summons to oral proceedings, the Parties' attention further to document

D2: FR-A-2 379 104,

cited in the European Search Report.

VI. Oral proceedings were held before the Board, at the end of which the Appellant (Opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The Respondent (Patentee) requested that the appeal be dismissed and that the Opposition be rejected (main request); or that the patent be maintained in amended form

- a) with Claim 1 and col. 5 of the description presented at the oral proceedings as first auxiliary request, the rest of the patent specification being unamended (first auxiliary request); or
- b) with Claims 1 to 16 and col. 5 of the description presented at the oral proceedings as second auxiliary request, the rest of the patent specification being unamended (second auxiliary request).

VII. Claim 1 of the main request reads as follows:

"1. Apparatus for programming a cardiac pacing generator to effect a threshold mode of operation in which the minimum energy level required for the generated stimulating pulses to stimulate the patient's heart is determined, comprising keyboard means (22, 24, 26) for operating said programming apparatus in its threshold mode of operation; transmitter means (34) arranged to transmit encoded signals from said apparatus indicative of the desired energy level of the pacing pulses to be applied by said pacing generator to the patient's heart, conductor means (52a, b, c) for coupling said programmer to the patient for receiving and detecting the patient's heart activity signals including the stimulating pulses applied to the patient's heart by said pacing generator, display means (28) for displaying the energy level of the stimulating pulses as applied to the patient's heart, and computing means (32) responsive to the initiation of

operation in the threshold mode by said keyboard means for decrementing the current value of the energy level by a predetermined amount and causing said transmitter means to transmit a new encoded signal commanding said pacing generator to apply stimulating pulses of the decremented energy level."

Claims 2 to 17 are dependent on Claim 1.

VIII. Claim 1 of the first auxiliary request corresponds to Claim 1 of the main request amended as follows:

inserting after "computing means (32) responsive to the initiation of operation in the threshold mode by said keyboard means for decrementing the current value of the energy level" in line 53 of column 34 of the patent specification, the words: "held in the apparatus".

Claims 2 to 17 are dependent on Claim 1.

IX. Claim 1 of the second auxiliary request corresponds to Claim 2 of the main request, i.e. to the wording of Claim 1 of the main request wherein after its last words "decremented energy level", the following wording is added:

"and further including means for counting the number of stimulating pulses applied by said pacing generator to the patient's heart and arranged after a predetermined count to cause said computing means to decrement the current energy level by the predetermined amount."

Claims 2-16 are dependent on Claim 1.

- X. With regard to the Respondent's (Patentee's) main and first auxiliary requests the appellant (Opponent) argues mainly as follows:
- a) Claims 1 of the Respondent's main and first auxiliary requests contain the same subject-matter, the amendment introduced according to the first auxiliary request being a mere clarification of the wording of Claim 1 of the main request.
 - b) In view of the completely automatic measurement of the threshold energy of a pacing pulse for stimulating cardiac contraction in document D1, the manual control of the pulse energy decreasing step as claimed in the patent under appeal would technically be no further development of the heart pacemaker art, but only allow - in a foreseeable way - a more precise control of the pulse energy applied in each decremental step.
 - c) Due to the fact that an external manual control of the energy of the pacing pulses is already known from document D2, a skilled person only would have to provide a new key in the known keyboard for automatically decrementing the current pulse energy by a predetermined amount. Such measures and the corresponding reorganisation of the known external computing means would be within the expert's normal skill.
 - d) The normal task in practice, to simplify the structure of an implanted pacemaker - and quite usual energy considerations would lead a skilled person to take the means for realising the threshold mode with its stepwise reduction of the pacing pulse energy out of the implanted pacemaker - as known from

document D1 - and to insert them into the external programmer - as known from document D2.

XI. As far as his main and first auxiliary requests are concerned, the Respondent (Patentee) takes the following view;

- a) Document D2 neither mentions explicitly cardiac stimulation nor is the pulse energy decrementing, mentioned in this document, page 49, line 40 to page 50, line 5 an automatic adjustment. Hence, an external command means for successive, automatically decremented pulse energy values as claimed in Claim 1 of the present invention would not be known from document D2.

- b) Document D1 teaches to realise a threshold mode operation within the implanted pacemaker itself. Thus, a combination of the teachings of documents D1 and D2 would rather result in an apparatus which triggers from outside a pacemaker circuit for actuating automatically repetitive decrements of the pulse energy down to its threshold value for cardiac stimulation but not in the apparatus claimed in Claim 1. The cited prior art would give no hint to provide command means for an automatic stepwise, energy decrease of the pacing pulses within an external programmer. For this reason, it would not be obvious to transfer the internal command means for a threshold mode of operation known from document D1 to the external programmer known from document D2, and to adapt the logic of the known external computing means in order to produce a command signal for a pacing pulse energy level the current value of which is decremented by a predetermined amount.

- c) In view of the prior art known from documents D1 and D2, the apparatus according to the claimed invention would produce remarkable advantages. In the apparatus claimed in Claim 1 the patient's heart activity signals and the energy level of the stimulating pulses are displayed simultaneously. In the apparatus known from document D2 a simultaneous display of the read-out energy and of the biopotentials would not be possible, see D2, page 38, lines 9-11. Contrary to the device known from document D1, wherein the charging time of transistor C3 in figure 4 cannot be altered, the apparatus according to the present invention would allow to vary the amount, by which the current pacing pulse energy level is decremented.

XII. Concerning the Respondent's second auxiliary request, the Appellant presents the following arguments:

- a) It is known from document D1 to decrement the current energy level of a pacing pulse after n counted stimulating pulses with $n = 1$. Substituting "1" by a different number would be not inventive but within the discretion of the user.
- b) The keying-in of an individual command signal for each explicit energy level of a pacing pulse in the apparatus known from document D2 gives the user the possibility to determine himself the time of the next energy decrement. In reorganising this known apparatus according to the teaching of document D1, a user would maintain this advantage and make the count n as large as the time he would need for observing the response of the patient's heart.

XIII. In support of his second auxiliary request the Respondent argues as follows:

- a) A waiting time corresponding to a predetermined number of stimulating pulses before each subsequent decrement of the pacing pulse energy level is not mentioned in the prior art documents cited.
- b) This waiting time would slow down the actuation of subsequent energy decrements, and thereby make it more convenient for the user to observe the performance of the patient's heart and allow furthermore the heart to stabilise its reaction to the decremented pulse energy. Both these facts would result in a more accurate determination of the actual threshold value of the pacing pulse energy.

Reasons for the Decision

1. The appeal is admissible.
2. **Novelty - Main and First Auxiliary Requests**
 - 2.1 From document D2 there is known, using the terminology of Claims 1 of the Respondent's main and first auxiliary requests, an

"Apparatus (see 22 in Fig. 1 of D2 as well as Fig. 17) for programming a cardiac pacing generator (10 in Fig. 1) to effect a threshold mode of operation in which the minimum energy level required for the generated stimulating pulses to stimulate the patient's heart is determined, comprising keyboard means (264, 262 in Fig. 17 of D2) for operating said programming apparatus (D2, page 46, lines 21 to 26), transmitter means (302 in Fig. 17, 26 in Fig. 1) arranged to transmit encoded signals (Fig. 3a) from said apparatus

indicative of the desired energy level (see parameters amplitude and pulse width mentioned on page 46, line 23) of the pacing pulses to be applied by said pacing generator to the patient's heart; means (304, 311 in Fig. 17 and page 49, lines 37 to 39) for coupling said programmer (22 in Fig. 1) to the patient for receiving and detecting the patient's heart activity signals including the stimulating pulses applied to the patient's heart by said pacing generator (see Fig. 1, 15a, 15b, 40, 38, 32, 25, 26 and page 12, lines 26 to 32), display means (306 in Fig. 17) for displaying the energy level of the stimulating pulses as applied to the patient's heart (page 49, lines 23 to 32, and page 12, lines 11 to 24) and computing means (274, 260, 266) responsive to the initiation of operation by said keyboard means for decrementing the current value of the energy level (page 49, line 40 to page 50, line 5), and causing said transmitter means (302) to transmit a new encoded signal commanding said pacing generator to apply stimulating pulses of the decremented energy level".

Though the text of document D2 uses the general terms "human tissue stimulator 10" implanted under the patient's skin (page 10, lines 19 and 20) instead of pacing generator, and "biopotential signals" from the stimulated tissue (page 12, line 27) instead of heart activity signals, the Board is convinced that a skilled person is able to deduce from the description of the technical means in document D2, that this known (external) apparatus is suitable for programming a cardiac pacing generator and that the known means for coupling the programmer to the patient is suitable for receiving and detecting the patient's heart activity signals. The Respondent has put forward no convincing arguments which establish credibility of the contrary, see point XI-a above.

The text of document D2 does not mention any measures to determine the minimum energy level for heart stimulation. However, in the Board's view a skilled person easily deduces from the disclosure of the technical means in document D2 that this known (external) apparatus for programming is suitable for programming an (internal) cardiac pacing generator in such a way that it effects "a threshold mode of operation". For this purpose the user has to actuate the key for the parameter "pulse amplitude" in parameter keyboard 264 of Figure 17 and to manually insert into value keyboard 262 of Figure 17 a series of explicit numerical values in response to which decremental alterations of the pulse amplitude are effected (see document D2, page 49, line 40 to page 50, line 21) and to verify after each insert whether heart capture occurs in analog display 311 of Figure 17.

2.2 Thus, the subject-matter of Claims 1 of the Respondent's main and first auxiliary requests differs from the apparatus according to document D2 in that:

- a) the claimed "keyboard means" for operating the programming apparatus comprise keyboard means for operating said programming apparatus "in its threshold mode of operation", (col. 34, lines 37 and 38) i.e. individual keyboard means, which - upon actuation - initiate an automatic decrement of the "current value of the energy values by a predetermined amount", and

the claimed "computing means are responsive to the initiation of" operation in the threshold mode by said keyboard means "for decrementing the current value of the energy level - held in the apparatus (as specified by the Respondent's first auxiliary

request) - by a predetermined amount" (col. 34, lines 49 to 53) i.e. contrary to the prior art known from document D2 no new explicit energy value has to be manually inserted for a decrement of the pulse energy but the current value of the energy level held in the apparatus is upon actuation of the threshold mode key automatically decremented by a predetermined amount in the computing means before transmitting the corresponding new encoded signal which commands the pacing generator (see also point XI-a above); and

- b) the claimed apparatus uses "conductor" means instead of wireless transmission means for coupling said programmer to the patient for receiving and detecting the patient's heart activity signals and the stimulating pulses applied.

2.3 Document D1 describes an "apparatus for programming a cardiac pacing generator to effect a threshold mode of operation in which the minimum energy level required for the generated stimulating pulses to stimulate the patient's heart is determined", see document D1, Figure 2A, B and C and the description, page 7, paragraphs 1 and 2, and page 15, paragraph 3, to page 16, paragraph 2. This known apparatus comprises keyboard means (see S in Fig. 6) for operating not the programming apparatus but the implanted pacing generator in its threshold mode of operation, and the computing means, being responsive to this keyboard means for decrementing the current value of the energy level by a predetermined amount are not located in the external programming apparatus but in the implanted pacing generator (see circuit C in Figures 4 and 8). The known transmitter means do not transmit a new encoded signal for each decremented energy level, but a trigger signal for a Reed-switch (see for instance RE1 in Figure 8), which initiates a series of

automatic subsequent decrements of the pulse energy level by a predetermined amount, down to the threshold value (see 1.2 mA in Figure 2 C). This known device uses like the claimed one "conductor" means (see EL in Figure 7 and page 18 lines 9 to 19) for receiving and detecting heart activity signals and stimulating pulses. However, document D1 is silent about display means for the energy level of the stimulating pulses applied.

2.4 The remaining documents cited in the European Search Report do not come closer to the subject-matter of Claims 1 of the Respondent's main and first auxiliary requests. In particular, none of these documents mentions any measures or means to effect said threshold mode of operation.

2.5 For these reasons, the subject-matter of Claims 1 of the Respondent's main and auxiliary requests is considered to be novel in the sense of Article 54 EPC.

3. Inventive Step - Main and First Auxiliary Requests

3.1 The nearest prior art, in the Board's view, is constituted by the apparatus for programming described in document D2.

Starting from this state of the art, the objective problem underlying the present invention as claimed in Claims 1 of the Respondent's main and first auxiliary requests is to simplify board means for effecting a threshold mode of operation. In the Board's view, a simplification of the handling of a known apparatus is a normal routine task in practice. Therefore, no positive contribution to inventive step can be seen in formulating this technical problem.

- 3.2 This problem is solved by the distinguishing feature (a) already mentioned in point 2.2 above, i.e. in that a separate means is provided within the known keyboard for starting the threshold mode of operation and in that the known computing means are made responsive to said separate keyboard means and are reconstructed for automatically decrementing the current value of the energy level by a predetermined amount in order to command the pacing generator accordingly.
- 3.3 Distinguishing feature (b) indicated in point 2.2 does not contribute to the above mentioned problem and its solution. The substitution of the wireless transmission means (32, 25, 26 in Fig. 1 of document D2) by "conductor" means (such as electro-cardiographic electrodes EL in Fig. 7 of document D1) is regarded as an obvious use of a well-known equivalent.
- 3.4 The known separate actuation means for the threshold mode of operation in the apparatus according to document D1 (see S in Figure 6 of D1) in the Board's opinion clearly show to a skilled person the advantage of a one-key-command for the threshold mode and will incite him to provide such separate actuation means also within the keyboard means of the apparatus known from document D2. In order to arrive at the subject matter of Claim 1 a skilled person would additionally have to transfer the means for automatically decrementing the current pacing energy by a predetermined amount within the command signal (C in Fig. 4 of D2) of pacing pulse generator (V in Figure 4 of D2) from the implanted pacemaker (i.e. the prior art according to document D1) into the external computing means (260, 266, 274) of the apparatus known from document D2; see also point XI-b above.

3.5 The Board regards a skilled person as being able to differ between the essential teaching of document D1 with regard to a command for an automatic predetermined pulse energy decrement and its actual realisation by means located within the pacemaker. In the event that a known programmer-stimulator-system, such as the one described in document D2, has no means for automatically changing the command signal in order to effect a pulse energy decrement, a skilled person in the Board's view will easily recognise that such means may be provided as well in the pacer as in the programmer. The Board is convinced that in the pacemaker art a skilled person is aware of the space problem caused by providing additional circuits within the implanted casing of the pacemaker and therefore will rather tend to install means, which do not have to be obligatorily implanted, outside the human body. Moreover, due to the fact that in the programmer known from document D2 external means for manually decrementing the pulse energy signal of a command transmitted to an implanted stimulator already exist, a skilled person will rather be guided to arrange for their automatic functioning instead of providing additionally a completely new separate transmission line for a trigger signal for threshold mode operation, and a second set of decrementing means for the pulse energy in the implanted stimulator. Hence, in the Board's opinion a skilled person as a result of normal considerations for a feasible and technically reasonable realisation of the teaching of document D1 in the apparatus according to document D2 will rather select the external position of said automatically decrementing means out of the existing two possibilities. The Board is convinced that such a pragmatic thinking can be expected from a skilled person on the basis of his normal abilities and does not need any technical creativity of inventive character.

3.6 The advantages put forward by the Respondent as set out under point XI-c above are technically not achievable by the means claimed in Claims 1 of the Respondent's main and first auxiliary requests. The wording of both these claims is strictly limited to a display of only the pulse energy value (see Col. 34, lines 47-49) and does not define a possibility to vary the predetermined amount by which the current value of the energy level is decremented. Therefore, these advantages are not relevant for considering the existence of an inventive step in the subject-matter of said claims.

3.7 For the reasons indicated in detail in points 3.1 to 3.6 above, the subject-matter of Claim 1 of the Respondent's main request and of Claim 1 according to the Respondent's first auxiliary request is held to be the use of a known technology in a closely analogous situation, accompanied by adaptation measures which fall within the normal skill of the expert. Therefore, the subject-matter of both claims is considered to lack an inventive step within the meaning of Article 56 EPC.

4. Hence, the Respondent's main and first auxiliary requests have to be rejected.

5. Second Auxiliary Request

5.1 Claim 1 of the Respondent's second auxiliary request comprises the subject-matter of granted Claims 1 and 2 and is based on features disclosed in originally filed Claims 1, 8 and 9. Thus, there is no objection to the current version of this claim as far as Articles 123(2) and 123(3) EPC are concerned.

Also the dependent claims and the description according to the Respondent's second auxiliary request are

adequately based on the original disclosure. These facts were not disputed by the Appellant either.

5.2 Novelty - Second Auxiliary Request

In addition to the distinguishing features (a) and (b) mentioned in point 2.2 above, the subject-matter of Claim 1 of the Respondent's second auxiliary request differs from the apparatus of the nearest prior art as described in document D2 in that the claimed apparatus includes:

- c) "means for counting the number of stimulating pulses applied by said pacing generator to the patient's heart and arranged after a predetermined count to cause said computing means to decrement the current energy level by the predetermined amount."

The apparatus known from document D2 does not count the stimulating pulses in order to keep their energy constant for a predetermined number of pulses before an automatic decrement is actuated but reduces the energy of each subsequent stimulating pulse by the predetermined value see D2, figure 2C. With regard to the remaining documents to be considered reference is made to points 2.3 and 2.4 above.

Hence, the subject-matter of Claim 1 of the Respondent's second auxiliary request is considered to be novel in the sense of Article 54 EPC.

5.3 Inventive Step - Second Auxiliary Request

Starting from the nearest prior art according to document D2, the objective problem underlying the present invention as claimed in Claim 1 of the Respondent's second auxiliary

request is to effect in a simple way of handling a threshold mode of operation, which increases the reliability of the determined minimum energy value for heart stimulation. This problem is solved by the distinguishing features (a) mentioned in point 2.2 above and (c) mentioned in point 5.2 above.

Document D1, the only document on file dealing with said threshold mode of operation for determining the minimum energy required for stimulating a patient's heart, decrements the current value of the energy level in each subsequent stimulating pulse. Whenever heart capture is lost, the stimulating pulse energy is automatically incremented to the original start value and stepwise decremented for a second time. In order to increase the reliability of the observed minimum energy level for heart capture document D1 teaches a repetition of the subsequent constant decrements each beginning at the re-established start value, so that the enveloping curve of the pulses is of the ratchet-type; see D1, figures 2 A, B, C. In the Board's view, a repetition of subsequent decrements does not hint a skilled person to keep the pulse energy constant for a predetermined number of stimulating pulses before actuating the decrement. Having regard to the Appellant's arguments (see Point XII above), the Board is of the opinion that in view of the prior art known from documents D1 and D2, a user - for reasons of convenience - would rather delay the start time of a complete series of automatic subsequent decrements down to the minimum energy value for heart capture than delay the time of each individual decrement.

For these reasons the Board finds that the subject-matter of Claim 1 involves an inventive step within the meaning of Article 56 EPC.

- 5.4 Hence it follows that Claim 1 of the Respondent's second auxiliary request is allowable.

Dependent Claims 2-16 concern particular embodiments of the apparatus according to Claim 1 and are likewise allowable.

Accordingly, the Respondent's second auxiliary request can be allowed.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The Respondent's main and first auxiliary requests are rejected.
3. The case is remitted to the First Instance with the order to maintain the patent as amended according to the Respondent's second auxiliary request, i.e. with Claims 1 to 16 and column 5 of the description presented at the oral proceedings held on 11 September 1990 as second auxiliary request, the rest of the patent specification being unamended.

The Registrar:

The Chairman:

P. Martorana

K. Lederer