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Bezeichnung der Erfindung:
Title of invention:
Titre de l'invention : Apparatus for controlling cardiac ventricular tachyarrhythmias

Klassifikation / Classification / Classement : A61 N1/38, A61 N1/04

ENTSCHEIDUNG / DECISION

vom / of / du 21 January 1988

Anmelder / Applicant / Demandeur : Medtronic Inc.

Patentinhaber / Proprietor of the patent /
Titulaire du brevet :

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence :

EPÜ / EPC / CBE Article 56 EPC

Kennwort / Keyword / Mot clé : "Inventive step (Yes); selection of three small ranges of independent parameters in a technical field permitting only a limited number of trials"

Leitsatz / Headnote / Sommaire

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Case Number : T 348/86

D E C I S I O N
of the Technical Board of Appeal 3.4.1.
of 21 January 1988

Appellant : Medtronic Inc.
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U.S.A.

Representative : Dr. Ing. Hans H. Wilhelm
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Decision under appeal : Decision of Examining Division 040 of the European Patent Office dated 29 April 1986 refusing European patent application No. 83 105 192.5 pursuant to Article 97(1) EPC

Composition of the Board :

Chairman : K. Lederer
Members : E. Turrini
O. Bossung

Summary of Facts and Submissions

I. European patent application 83 105 192.5 (publication number 0 095 726) was refused by decision of the Examining Division of the European Patent.

II. The decision under appeal was based on Claims 1 to 4 as filed on 28 August 1985.

III. The reason given for the refusal was that in view of the prior art documents

FR-A-2 257 312 (D1) and
US-A-3 359 984 (D2),

the subject-matter of Claim 1 did not involve an inventive step within the meaning of Article 56 EPC and the claim was thus not allowable under Article 52(1) EPC.

IV. An appeal was lodged against the decision.

V. An oral proceedings was held, in which the appellant requested that the decision of the Examining Division be set aside and a European patent be granted on the basis of Claims 1 to 4, handed over in the oral proceedings.

VI. Current Claim 1 of the main request reads as follows:

"1. An implantable defibrillator for controlling cardiac ventricular fibrillation or other tachyarrhythmias by passing an electric current through the heart, comprising a plurality of electrode pairs (10, 11, 21, 22) disposable around the heart and means (28) for sequentially pulsing the pairs, characterised in that each of the pairs of electrodes (10, 11, 21, 22) is subjected to pulses at a

voltage between about 100 and about 400 volts, providing a current above the defibrillation threshold level, the pulses being separated by an interval of about 0.1 millisecond to about 2 milliseconds and having a duration of about 1 millisecond to about 5 milliseconds."

Claims 2 to 4 are dependent on Claim 1.

VII. The Appellant argued that indeed document D1, similarly to the defibrillator of the invention, refers to a defibrillator having a plurality of electrode pairs disposable around the heart, to which sequential pulses are supplied. However, the skilled man wishing to control the cardiac ventricular fibrillation more safely and in a more effective manner, would not seek solutions starting from D1, because the value ranges of the three parameters, i.e. applied voltage, pulse duration and interval between pulses, mentioned in D1 are so broad and vague that they are not usable as starting point. In other words, it is impossible to reach the invention starting from D1 simply by trial and error, due to the great number of necessary trials and due to the fact that in this special technical field experiments are difficult to realize, i.e. the result has to be achieved with a limited number of experiments. Moreover, in D1 there is no additional teaching which gives the skilled man any hint pointing at the claimed value ranges and the two prior art documents "Ventricular Defibrillation, a new aspect", Acta Chirurgica Scandinavia, Stockholm, 1967, Jan Kugelberg (A1) and "The effect of shock separation time on multiple-shock defibrillation", Medical Instrumentation, Volume 12, No. 1, January-February 1978, Moore et al. (A2), suggest, in case of human treatment, pulse intervals much greater than those claimed in Claim 1, i.e. A1 and A2 point away from the invention.

Reasons for the Decision

1. The appeal is admissible.

2. There is no objection to the current set of claims as far as Article 123(2) EPC is concerned, since they are adequately supported by the original disclosure. In particular, present Claim 1 is supported by original Claims 7, 9 and 10 and by the original description, page 4, line 2 and page 12, first paragraph.

3. Novelty.

3.1. Document D1 (Figures 1 and 6; pages 4 to 8 and 14 to 16 of the description) describes a defibrillator for controlling cardiac ventricular fibrillation by passing an electric current through the heart (page 4, lines 19 to 22) comprising a plurality of electrode pairs (10) disposable around the heart (page 5, lines 17 to 22) and means for sequentially pulsing the pairs (page 4, lines 23 to 27, page 6, lines 17 to 24, page 8, lines 26 to 35). The defibrillator is also implantable, i.e. it is possible to implant it in a body, due to the fact that its technical features are all compatible with an implantable defibrillator option. In this respect, the Board of Appeal cannot share the Appellant's view that the presence of a selector having three positions, namely two positions for automatic and manual operations and a third position for external command (Figure 1 and description, page 7, first paragraph) means that the defibrillator cannot be implanted. In the Board's opinion, in the embodiment of Figure 6, where the electrodes are implantable, there is no reason to consider the remainder of the defibrillator as not implantable. Neither the schematic representation in Figure 1 nor the description of the above mentioned

selector or of other parts of the defibrillator excludes an external telemetric command or other arrangements which allow implantation of the known defibrillator.

Therefore, all the features mentioned in the preamble of Claim 1 are known from this document.

Moreover, each of the pairs of electrodes (10) is subjected to pulses which can reach 2000 volts (page 14, lines 25 to 29), providing a current above the defibrillation threshold level, a fact not disputed by the Appellant. The pulses can be separated by an interval (page 15, line 4) and in this case the duration of every pulse is obviously less than 20 milliseconds (page 6, line 25: with the lowest pulse frequency of 50 Hz, the pulse period is 20 milliseconds and therefore the duration is less than 20 milliseconds when ever the pulses are separated by an interval.

The subject-matter of document D1 differs from the subject-matter of Claim 1 in that the ranges of voltage, pulse duration and pulse interval disclosed in D1 include but are broader than the ranges claimed in Claim 1.

3.2. Document D2 refers to an apparatus for controlling cardiac ventricular fibrillation by passing an electric current through the heart (column 1, lines 12 to 17), comprising two electrodes to be placed in contact with the patient's body in the vicinity of the chest (column 1, lines 16, 17, 46 and 47 and column 2, line 14), means (column 1, lines 50 and 51) for pulsing the voltage applied across the electrodes, said voltage being of the order of 2500 volts (column 1, line 67). The provided current must necessarily be above the defibrillation threshold level. The pulses are separated by an interval of about 6 milliseconds and the interval

duration is about 4 milliseconds, but these two values can be varied within desired limits (column 3, lines 64 to 69).

The subject-matter of document D2 differs from the subject-matter of Claim 1 in that the device of D2 has only two electrodes so that there is no sequential pulsing of the pairs. The defibrillator including the electrodes is not implantable, the voltage is much higher than the voltage range mentioned in Claim 1, and the ranges of pulse duration and interval are not exactly defined, even if they are of the order of magnitude of the ranges disclosed in Claim 1.

3.3. The other cited documents of the prior art and in particular A1 and A2, which do not mention the utilisation of more than one pair of electrodes and which emphasise the necessity of pulse intervals greater than 70-100 milliseconds in order to obtain successful results in case of human treatment, are not relevant with respect to the present invention.

3.4. For the above reasons the subject-matter of Claim 1 and consequently of the dependent Claims 2 to 4, is deemed to be novel within the meaning of Article 54 EPC.

4. Inventive step.

4.1. Claim 1 is based, as before outlined, on D1, which is, in the Board's opinion, the nearest prior art.

Starting from the disclosure of this document, the skilled man is faced with the problem of obtaining successful defibrillation results, by reducing the risk of possible damage to the heart and at the same time reducing the energy requirements. The problem is solved

by choosing the pulse parameters, i.e. the pulse voltage, the interval between pulses and the pulse duration, as set out in the characterising portion of Claim 1, so as to reduce the energy of a single peak and the total energy to the heart and consequently, the risks of myocardial damage and so as to reduce also the size of the defibrillator.

4.2. The solution to this problem is considered to involve an inventive step for the following reasons.

Although the ranges of the three parameters, pulse voltage, pulse duration and pulse interval according to document D1 include the ranges set out in Claim 1 and although this is the only difference between the defibrillator disclosed in document D1 and the defibrillator of Claim 1, it has to be considered that the quantitative difference of the range values in the two cases is considerable: while in the defibrillator of document D1 the voltage range covers the values from 0 to 2000 volts, the pulse duration covers the time range between 0 and 20 milliseconds and the pulse interval covers a range between 0 and 20 milliseconds, in the defibrillator of Claim 1 the ranges are much lower, i.e. between 100 and 400 volts, between 1 and 5 milliseconds and between 0.1 and 2 milliseconds respectively.

In order to obtain the invention, the skilled man should firstly realise that a selective choice of ranges among those provided by the disclosure of D1 would likely solve the problem. Document D1 does not give any hint in this respect. But even if it did, he should, secondly, effect a great number of experiments by merely applying the trial and error criterion, because he would not dispose of any better criterion helping him to move in the right direction.

In the present case, the particular medical field, where the experiments necessarily have to be effected first on live animals and then on human beings, in difficult operative conditions, i.e. under anaesthesia, with open heart etc., forbids such a great number of trials.

Only chance or a forecast, beyond the capability of a "skilled man", would allow one to start from a point reasonably near the right ranges of values, so as to reach the invention with an acceptable number of experiments.

On the other hand, document D2 would not help to render the subject-matter of Claim 1 obvious. It is true, as stressed by the Examining Division in the impugned decision, that the range values concerning the pulse duration and the pulse interval are of the order of magnitude of those set out in Claim 1. However, document D2 refers to a non-invasive defibrillator, i.e. it discloses a paddle defibrillator, where the paddles are placed on the surface of the patient's chest. Moreover, document D2 discloses only one pair of paddles, so that there is no sequential pulsing of the pairs. The current distributions in the heart are therefore fully different from and not comparable with those disclosed in document D1, in case of implantable electrodes. A combination of the teachings of the two documents is thus not admissible.

The other cited documents, in particular documents A1 and A2, which do not refer to defibrillators with a plurality of electrode pairs and which, in any case, give results pointing away from the invention (they suggest pulse

intervals much greater than those claimed in Claim 1, as already mentioned), do not help to solve the above mentioned problem either.

4.3. Thus, the subject-matter of Claim 1 is considered to involve an inventive step within the meaning of Article 56 EPC and Claim 1 is, therefore, admissible under Article 52(1) EPC.

4.4. Claims 2 to 4 relate to particular embodiments of the invention. They are, therefore, also allowable under Article 52(1) EPC as dependent claims in agreement with Rule 29(3) 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 grant a patent with the following text:

- Description, pages 1 to 14 handed over in the oral proceedings on 21 January 1988;

- Claims 1 to 4 handed over in the oral proceedings on 21 January 1988;

- Drawings, original Figures 1 to 12.

The Registrar: The Chairman:

F.Klein K.Lederer