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**D E C I S I O N**  
**of 14 December 2004**

**Case Number:** T 0465/02 - 3.4.1

**Application Number:** 93250120.8

**Publication Number:** 0594269

**IPC:** A61N 1/39

**Language of the proceedings:** EN

**Title of invention:**

Atrial defibrillator for providing interval timing prior to cardioversion

**Patentee:**

Cardiac Pacemakers, Inc.

**Opponent:**

Biotronik GmbH & Co. KG

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 100(a), 52(1), 56

**Keyword:**

"Inventive step - no"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 0465/02 - 3.4.1

**D E C I S I O N**  
of the Technical Board of Appeal 3.4.1  
of 14 December 2004

**Appellant:**  
(Opponent)

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**Representative:**

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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 2002  
rejecting the opposition filed against European  
patent No. 0594269 pursuant to Article 102(2)  
EPC.

**Composition of the Board:**

**Chairman:** G. Davies  
**Members:** R. Q. Bekkering  
H. K. Wolfrum

## Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the decision of the opposition division, dispatched on 4 March 2002, rejecting the opposition against European patent No. 0 594 269. The notice of appeal was received on 30 April 2002, the appeal fee being paid on the same day, and the statement setting out the grounds of appeal was received on 10 July 2002.
- II. Opposition had been filed against the patent as a whole, based on Articles 100(a), (b) and (c) EPC.
- III. In the appeal proceedings reference was *inter alia* made to the following documents:
- D1: WO-A-92 14512  
D2: B. Lüderitz, "Elektrische Stimulation des Herzens", SpringerVerlag, 1980, pages 319, 320  
D6: US-A-4 577 633  
D7: US-A-4 595 009  
D8: US-A-4 865 036  
D9: US-A-4 830 006
- IV. Oral proceedings were held on 14 December 2004.
- V. The appellant requested that the decision under appeal be set aside and the patent revoked.
- VI. The respondent requested that the appeal be dismissed and that the patent be maintained as granted (main request).

Alternatively, it was requested that the patent be maintained in amended form on the basis of the following documents:

First auxiliary request:

Claims: Claims 1 to 8 as filed in the oral proceedings on 14 December 2004;

Description and drawings as granted.

Second auxiliary request:

Claims: Claim 1 (marked "First Auxiliary Request") as filed with the letter dated 12 November 2004;

Claims 2 to 9 as granted;

Description and drawings as granted.

Third auxiliary request:

Claims: Claim 1 (marked "Second Auxiliary Request") as filed with the letter dated 12 November 2004;

Claims 2 to 9 as granted;

Description and drawings as granted.

Fourth auxiliary request:

Claims: Claim 1 (marked "Third Auxiliary Request") as filed with the letter dated 12 November 2004;

Claims 2 to 9 as granted;

Description and drawings as granted.

VII. Claim 1 as granted (main request) reads as follows:

*"An atrial defibrillator for providing cardioverting electrical energy to the atria of a human heart, including a first detector (34, 38, 40, 50, 52) for detecting activations of the heart and a cardioverting mechanism (36, 44, 46, 74, 76) for applying cardioverting electrical energy to the heart, the first detector (34, 38, 40, 50, 52) is configured to detect ventricular activations; the cardioverting mechanism (36, 44, 46, 74, 76) is configured to apply cardioverting electrical energy to the atria of the heart; characterized in that: an electronic control (62) is electrically coupled to the first detector (34, 38, 40, 50, 52) and the cardioverting mechanism (36, 44, 46, 74, 76) so that said control (62) is responsive to an electrical signal from the first detector (34, 38, 40, 50, 52) and is configured to activate the cardioverting mechanism (36, 44, 46, 74, 76) when the time between immediately successive ventricular activations detected by the first detector (34, 38, 40, 50, 52) is greater than a preselected time interval."*

VIII. Claim 1 according to the first auxiliary request corresponds to claim 1 as granted with the following additional features:

"and the immediately successive ventricular activations include a first ventricular activation and an immediately following second ventricular activation, and control (62) is configured to activate the cardioverting mechanism (36, 44, 46, 74, 76) to apply the cardioverting electrical energy to the atria of the heart substantially coincident with the second ventricular activation."

- IX. The claims 1 according to the second, third and fourth auxiliary request correspond to claim 1 as granted with the following amendments to the last feature of the characterising portion (emphasis added):

(second auxiliary request)

"and is configured to activate the cardioverting mechanism (36, 44, 46, 74, 76) when **a single measured time intervall [sic] between two** immediately successive ventricular activations detected by the first detector (34, 38, 40, 50, 52) is greater than a preselected time interval."

(third auxiliary request)

"and is configured to activate the cardioverting mechanism (36, 44, 46, 74, 76) **so as to initiate the application of cardioverting electrical energy to the atria of the heart** when the time **intervall [sic]** between **two** immediately successive ventricular activations detected by the first detector (34, 38, 40, 50, 52) is greater than a preselected time interval."

(fourth auxiliary request)

*"and is configured to activate the cardioverting mechanism (36, 44, 46, 74, 76) so as to initiate the application of cardioverting electrical energy to the atria of the heart when a single measured time intervall [sic] between two immediately successive ventricular activations detected by the first detector (34, 38, 40, 50, 52) is greater than a preselected time interval."*

- X. The appellant argued that the subject-matter of claim 1 as granted was rendered obvious by the teaching of document D1 in combination with the teachings of any one of documents D6 to D9. In particular, the subject-matter of claim 1 only differed from the atrial defibrillator known from document D1 in that in the claimed device the cardioverting mechanism was activated when the time between immediately successive ventricular activations (R-waves) was greater than a preselected time interval, whereas in D1 the cardioverting mechanism was activated when the presence of a ventricular tachycardia was ruled out. The use of a criterion for the detection of a ventricular tachycardia based on the comparison of one or of several consecutive R-R-intervals was suggested in any one of documents D6 to D9. Moreover, at any rate claim 1 as granted was not limited to the comparison with only a single interval. Claim 1 was furthermore also not considered to require synchronism between the defibrillation pulse and the last detected R-wave. In any case, synchronised defibrillation was entirely common, as shown by document D2, and used in the device shown in document D1. The claims 1 of the auxiliary

requests merely added the above features, relating to the R-R-interval considered and the synchronised defibrillation, in more or less detail and, therefore, also lacked inventive subject-matter.

- XI. The respondent submitted that none of the cited documents described or suggested an atrial defibrillator wherein an atrial cardioverting mechanism was activated when the time interval between immediately successive ventricular activations was greater than a preselected interval. In particular, none of the cited documents addressed the problem solved by the device defined in granted claim 1 of avoiding the delivery of atrial fibrillation in "R on T" conditions in which the R-wave was closely spaced from the preceding T-wave, as this could induce ventricular fibrillation. Although document D1 suggested that atrial cardioversion could be disabled in response to the reliable identification of a ventricular tachycardia or ventricular fibrillation, it only did so in order to deliver ventricular defibrillation. Furthermore, D1 did not describe or suggest how this identification could be done. As shown by documents D6 to D9, ventricular tachycardias were only reliably detected by considering a number of consecutive R-R-intervals. Although being already clear from claim 1 as granted, claim 1 of the first auxiliary request, as well as of the second to fourth auxiliary requests, in even more explicit terms defined the single R-R-interval to be compared with the preselected time interval and the delivery of the defibrillation pulse in coincidence with the last R-wave.



## Reasons for the Decision

1. The appeal complies with the requirements of Articles 106 to 108 and Rule 64 EPC and is therefore admissible.

2. *Main request*

2.1 From document D1, forming the closest prior art, an atrial defibrillator for providing cardioverting electrical energy to the atria of a human heart is known. In one of the embodiments (see figure 3; page 9, line 25 to page 11, line 4) the device is equipped with a detector for detecting ventricular activity, but with no detection of atrial activity. The delivery of cardioversion or defibrillation pulses to the atria is triggered externally by the patient or the physician in response to symptoms indicative of atrial tachycardia or fibrillation. An internal override is provided disabling the ability to trigger atrial cardioversion/defibrillation pulses in response to the internal detection of electrical activity in the ventricle, reliably identified as ventricular tachycardia or fibrillation rather than a high ventricular rate due to the atrial tachycardia or fibrillation.

An atrial defibrillator according to the pre-characterising portion of granted claim 1 of the patent in suit is thus known from document D1. As such, this is not in dispute between the parties.

2.2 The provision of an electronic control electrically coupled to the detector for ventricular activity and the atrial cardioverting means, so that the control is

responsive to an electrical signal from the detector, as defined in the characterising part of claim 1 as granted, is obvious, if not implicit, from D1 as part of the internal override provided for disabling the delivery of defibrillation pulses to the atria.

The respondent argued that in the device known from document D1 not only the triggering of the activation of the atrial defibrillation was done manually by the patient or a physician, but also the disabling of the delivery of atrial defibrillation pulses.

In document D1 the external triggering for enabling the delivery of atrial defibrillation pulses is performed by the patient or physician in response to the detection, by the patient or physician, of symptoms indicative of atrial tachycardia or fibrillation. As is well known in the art, typically the placement of an external magnet by the patient in proximity to the implanted device enables the defibrillation mechanism in the device starting the delivery of atrial defibrillation pulses synchronised and substantially coincident with the detected R-waves (see D1, page 8, lines 4 to 21). Nothing in the teaching of document D1 indicates that the embodiment of figure 3 would operate in a different manner.

The override, on the other hand, is provided internally of the implanted device and acts in response to an internal detection of ventricular activity.

Accordingly, the override provides an internal and automated control acting on the defibrillation mechanism and responsive to the ventricular detector, not relying on any manual intervention. Furthermore,

since conventionally the devices at issue are built from electronic components it would be at least obvious to implement the override by an electronic control.

- 2.3 Claim 1 as granted, furthermore, defines that the control is configured to activate the cardioverting mechanism when the time between immediately successive ventricular activations detected by the ventricular detector is greater than a preselected time interval.

As in substance argued by the appellant (see grounds of appeal, pages 3 and 4), in document D1, whenever the device is triggered externally, the cardioversion means are activated such that pulses are delivered, unless the cardioversion means are disabled as specified (see D1, paragraph bridging pages 10 and 11). The monitoring of the ventricular activity leads to a disabling of the cardioversion means only in case of identification of the ventricular activity as a ventricular tachycardia or fibrillation. Necessarily, in all other cases it leads to activation of the cardioversion means.

However, the criterion used to identify the ventricular activity as a ventricular tachycardia or fibrillation is not provided in document D1. In particular, document D1 does not mention the comparison of the time interval between successive ventricular activations and a preselected time interval.

Accordingly, the subject-matter of claim 1 as granted is novel over document D1. In fact, novelty was not in dispute in the present case.

2.4 Starting from a defibrillator as taught by document D1, the objective problem to be solved may be seen as providing such a criterion for identifying ventricular tachycardia.

A number of documents were cited by the appellant showing such criteria.

Documents D6 (see column 7, lines 5 to 62) and D7 (see column 5, line 66 to column 6, line 59) identify ventricular tachycardias by comparing the R-R-interval with a reference time interval. In both cases, if a number of consecutive R-R-intervals is shorter than a reference interval, a tachycardia is diagnosed.

A similar approach is taken in document D9, where a high rate indicative of ventricular tachycardia is detected by any number of one up to 255 consecutive intervals having a rate exceeding a selected base rate (see column 17, lines 45 to 54).

Finally, in document D8 (see column 4, lines 3 to 21) the presence of a ventricular tachycardia is detected by measuring the length of the last R-R-interval, converting it to a rate value and determining whether the measured rate is greater than a reference rate.

The use of such a known identification criterion for ventricular tachycardia in the device of document D1 would result in a device which, in the event of an atrial fibrillation, would continuously compare the most recent R-R-interval with a reference time interval and enable the atrial defibrillation when the R-R-interval is greater than the reference time interval.

Only in case the most recent R-R-interval, possibly together with a number of preceding, consecutive R-R-intervals, is shorter than the reference interval, would the atrial defibrillation be disabled.

Accordingly, the straightforward combination of the teaching of document D1 with that of any one of documents D6 to D9 would lead to a device falling under the terms of claim 1 as granted.

- 2.5 The respondent contested this finding, arguing that document D1 was primarily concerned with reliably detecting the presence of a ventricular fibrillation so as to deliver ventricular defibrillation pulses. In contrast thereto, the patent was concerned with avoiding the onset of a ventricular fibrillation caused by the delivery of an inappropriately timed atrial defibrillation pulse. Document D1 was therefore unrelated to the problem addressed by the patent in suit. Similarly, documents D6 to D9 were irrelevant to the invention in suit.

According to the patent in suit (see column 2, lines 41 to 47), at high cardiac rates, the R-wave of each cardiac cycle becomes closely spaced from the T-wave of the immediately preceding cardiac cycle. This may lead to a condition known in the art as an "R on T" condition which is believed to contribute to induced ventricular fibrillation if the atria are cardioverted in synchronism with the R-wave close to the T-wave. Evidently, a fundamental prerequisite for this problem to occur is the synchronised delivery of atrial defibrillation pulses, that is to say the atrial

defibrillation pulse delivery is substantially coincident with the detection of an R-wave.

As is well known in the art (see D2, page 319, last paragraph), synchronised delivery generally prevents the defibrillation pulse from being delivered on the T-wave, which may induce a ventricular tachycardia. However, in case of an "R on T" condition caused by high ventricular rates, it will result in the atrial defibrillation pulse being delivered on the T-wave.

Claim 1 as granted, however, does not prescribe that the atrial defibrillation pulse is delivered coincident with the last detected R-wave. In fact, this is a preferred further development of the invention defined in dependent claim 4 of the patent as granted.

The respondent argued in this respect that this synchronised delivery of the atrial defibrillation pulse was already clear from claim 1 as granted when interpreted in the light of the description and in particular in the light of the stated problem of avoiding the delivery of atrial defibrillation pulses in an "R on T" condition.

In the board's opinion it should however be clear that a claim providing a definition of the subject-matter of the invention in very broad terms, as is the case in the patent as granted, cannot be held to include further features of a preferred embodiment of the invention defined in a dependent claim. By providing these further features in a dependent claim, the patent proprietor clearly intended the subject-matter of

claim 1 to be more general, not including these further limitations.

The same applies obviously for further features of a preferred embodiment detailed in the description of the patent, whereby it should be noted that, contrary to what is held by the respondent, the fact that certain features would be indispensable for solving the problem indicated in the description cannot be held to imply that these features are consequently to be read into claim 1, but rather is an indication that either the problem to be solved stated in the description is excessively specific or that essential features for solving the problem are missing from the claim.

As such, the board can only agree with the appellant that the definition of the atrial defibrillator in claim 1 as granted indeed is very broad. Incidentally, it may be noted that granted claim 1 as such does not even require the provision of a detector for detecting the occurrence of an atrial fibrillation or make the delivery of the atrial defibrillation dependent on the presence of an atrial fibrillation. This is only part of the particular embodiment defined in dependent claim 5 as granted. Moreover, it should be noted that the patent in suit as such does not exclude the provision of ventricular cardioverting or defibrillating means.

Accordingly, in view of the breadth of claim 1 as granted, the alleged irrelevance of document D1 having regard to the patent in suit is not convincing.

2.6 Equally unconvincing is the alleged substantial difference between the activation of the atrial defibrillation according to claim 1 as granted and the disabling of the atrial defibrillation in document D1, argued by the respondent as well as the opposition division in the decision under appeal.

As discussed above, claim 1 as granted does not require that the atrial defibrillation pulse is delivered substantially coincident with the R-wave, but merely requires an unspecific activation of the cardioverting mechanism.

However, even assuming for the sake of the argument that the claim 1 were to define this activation to consist of the actual delivery of an atrial defibrillation pulse coincident with the R-wave, this would not lead to any substantial difference with respect to D1.

As noted above, in document D1, following the manual enabling of the defibrillator by the patient, the delivery of atrial defibrillation pulses, synchronised and substantially coincident with the detected R-waves, is started. The possibility of a disabling based on the detection of a ventricular tachycardia or fibrillation as such merely results in either the actual delivery of an atrial defibrillation pulse coincident with the R-wave, or the omission of the delivery, and is therefore not substantially different from the claimed activation.

2.7 Finally, the respondent argued that a combination of D1 and any one of documents D6 to D9 could result in an



atrial defibrillation pulse being delivered in an "R on T" condition, and would accordingly not solve the problem addressed by the present invention.

First of all, as discussed above, the claimed device actually does not necessarily avoid the delivery of an atrial defibrillation pulse in an "R on T" condition.

Moreover, only in case a criterion for detecting ventricular tachycardia based on several consecutive intervals being smaller than a reference interval is adopted in D1 and only under particular circumstances in which consecutive R-R-intervals are not systematically either smaller or greater than the reference value, the risk of delivering a defibrillation pulse in an "R on T" condition may arise. However, both from documents D8 and D9 it is apparent that the detection criterion for tachycardia may equally well be based on the consideration of only a single measured R-R-interval. In this case, even under the above particular circumstances, exactly the same operation of the device would result as that of a device according to claim 1 if limited to a synchronised delivery of the defibrillation pulses. It should be clear that the question as to how many R-R-intervals should be considered for deciding on the presence of a ventricular tachycardia is nothing but a common trade-off between complexity and accuracy, and as such cannot justify the recognition of the presence of an inventive step.

- 2.8 For the reasons given above, the subject-matter of claim 1 as granted lacks an inventive step (Articles 100(a), 52(1) and 56 EPC).

3. *First auxiliary request*

3.1 The appellant objected to the introduction of this request in view of its late filing. However, since the amendment merely consisted of the inclusion of the features of granted dependent claim 4 into the main claim, and since the amendment related to some of the issues discussed at the oral proceedings in relation to the main request, the board decided to nonetheless admit the request, as the amendments could neither be held to be inappropriate nor unforeseeable.

3.2 Claim 1 according to the first auxiliary request consists of granted claim 1 in combination with the further limitations of dependent claim 4 as granted. The requirements of Article 123(3) EPC are, thus, considered to be met. A basis for the amended claim 1 is provided by claims 1 and 5 as originally filed and the original description in general. Accordingly, the board is satisfied that the requirements of Article 123(2) EPC are met as well.

3.3 Claim 1 as amended in substance now specifies that the atrial defibrillation pulse is delivered substantially coincident with the last R-wave when the last R-R-interval is greater than the preselected time interval.

However, as already discussed above with respect to claim 1 as granted, these limitations do not render the subject-matter inventive.

3.4 Accordingly, also the subject-matter of claim 1 according to the first auxiliary request lacks an inventive step.

4. *Second, third and fourth auxiliary requests*

The amendments to claim 1 as granted in accordance with any one of these auxiliary requests, although in substance relating to the same technical aspects of the claimed device, are less restrictive than the amendments provided to claim 1 according to the first auxiliary request. These auxiliary requests, therefore, do not overcome the objections as to lack of inventive step raised with respect to the subject-matter of claim 1 according to the first auxiliary request.

5. In view of the above, none of the requests of the respondent are allowable.

**Order**

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

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

R. Schumacher

G. Davies