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**D E C I S I O N**  
**of 6 November 2002**

**Case Number:** T 1080/98 - 3.4.1

**Application Number:** 90303738.0

**Publication Number:** 0398488

**IPC:** A61N 1/365

**Language of the proceedings:** EN

**Title of invention:**  
Cardiac therapy device

**Patentee:**  
VENTRITEX, INC.

**Opponent:**  
Biotronik Mess- und Therapiegeräte GmbH & Co  
Ingenieurbüro Berlin

**Headword:**

-

**Relevant legal provisions:**  
EPC Art. 54, 56, 123(2)

**Keyword:**  
"Novelty - no (main request)"  
"Inventive step - no (first auxiliary request)"  
"Novelty and inventive step - yes (second auxiliary request)"

**Decisions cited:**

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**Catchword:**

-



Case Number: T 1080/98 - 3.4.1

**D E C I S I O N**  
**of the Technical Board of Appeal 3.4.1**  
**of 6 November 2002**

**Appellant:** Biotronik Mess- und Therapiegeräte GmbH & Co  
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**Respondent:** VENTRITEX, INC.  
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**Representative:** MacGregor, Gordon  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 22 September 1998  
rejecting the opposition filed against European  
patent No. 0 398 488 pursuant to Article 102(2)  
EPC.

**Composition of the Board:**

**Chairman:** G. Davies  
**Members:** M. G. L. Rognoni  
R. Q. Bekkering

## Summary of facts and submissions

- I. The appellant (opponent) lodged an appeal, received on 17 November 1998, against the decision of the opposition division, despatched on 22 September 1998, rejecting the opposition against the European patent No. 0 398 488. The fee for the appeal was paid on 17 November 1998 and the statement setting out the grounds of appeal was received on 29 December 1998.
- 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 independent claim 1 of the patent as granted met the requirements of Articles 52(1) and 54 EPC having regard to the following document:  
  
E2: EP-A-0 253 505
- IV. In response to a communication of the Board summoning the parties to oral proceedings, the respondent (patentee) filed auxiliary requests 1 to 6 by letter dated 3 October 2002, received on 4 October 2002.
- V. In the oral proceedings, which were held on 6 November 2002, the respondent filed a new second auxiliary request.
- VI. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

VII. The respondent requested that the appeal be dismissed and that the patent be maintained unamended (**main request**) or that the patent be maintained in accordance with one of the following auxiliary requests:

**first auxiliary request:**

claims 1 to 10 filed on 4 October 2002;

**second auxiliary request:**

claims 1 to 10 and pages 2 and 4 of the description filed in the oral proceedings with pages 3 and 5 to 7 of the description and Figures 1 to 5 as granted;

**third auxiliary request:**

claims 1 to 9 filed on 4 October 2002;

**fourth, fifth and sixth auxiliary requests:**

claims 1 to 9 respectively filed on 4 October 2002.

VIII. The wording of claim 1 according to the main request reads as follows:

*"1. An implantable cardiac pulse generator comprising:  
    means (71) for sensing a patient's heartbeat;  
    means (90) for determining the intervals between heartbeats;  
    storage means (93) including a plurality of storage count bins;  
    means (92) for assigning a count limit to each storage bin;  
    means (90) for detecting when a first bin reaches its count limit;  
    means (90) for providing a diagnosis of the patient's cardiac rhythm that is responsive to the*

*first bin to reach its count limit; and  
means (90) for initializing said storage bins;  
characterized by:  
each of said storage count bins corresponding to a  
different cardiac rhythm band; and  
means (90) for changing the count of the storage  
bin corresponding to the cardiac rhythm band of  
the determined heartbeat interval."*

Claims 2 to 6 are dependent on claim 1. Claims 7 and 8 are directed to a cardiac therapy device comprising the implantable cardiac pulse generator according to claim 1. Claims 9 and 10 are dependent on claim 8.

The wording of claim 1 according to the **first auxiliary request** differs from claim 1 of the **main request** essentially in that it recites:

*"means (90) for initialising said storage bins upon diagnosis of a cardiac rhythm"*

The wording of claim 1 according to the **second auxiliary request** reads as follows:

*"1. An implantable cardiac pulse generator comprising:  
means (71) for sensing a patient's heartbeat;  
means (90) for determining the intervals between  
heartbeats;  
storage means (93) including a plurality of storage  
count bins, each of the storage count bins  
corresponding to a different cardiac rhythm band;  
means (92) for assigning a count limit to each  
storage bin; means (90) for detecting when a first bin  
reaches its count limit;*

*means (90) for providing a diagnosis of the patient's cardiac rhythm that is responsive to the first bin to reach its count limit;*

*means (90) for initialising said plurality of storage bins upon said diagnosis of a cardiac rhythm; and*

*means (90) for changing the count of the storage bin corresponding to the cardiac rhythm band of the determined heartbeat interval, the plurality of storage bins simultaneously maintaining cumulative counts corresponding to each of the different cardiac rhythm bands between each diagnosis event."*

Claims to 2 to 6 are dependent on claim 1. Claims 7 and 8 are directed to a cardiac therapy device comprising the implantable cardiac pulse generator according to claim 1. Claims 9 and 10 are dependent on claim 8.

IX. The appellant argued essentially as follows:

Document E2 related to a pacemaker device comprising all the features recited in claim 1 according to respondent's **main request** and, in particular, counters or storage bins corresponding to different cardiac rhythm bands and providing diagnosis of a cardiac rhythm when a predetermined count limit was reached. In fact, there was essentially no difference between the counting of n consecutive heartbeat intervals or the counting of a predetermined number x of heartbeat intervals over y consecutive intervals, as disclosed in E2, and the "binning" technique taught in the contested patent. Hence, the subject-matter of claim 1 was not new within the meaning of Article 54 EPC.

In claim 1 according to the respondent's **first auxiliary request**, it was further specified that the cardiac pulse generator of the contested patent comprised means for resetting the count bins when a diagnosis was made. Figures 4 and 5 of E2 showed that the apparatus worked cyclically and that a therapy was administered after a cardiac event was sensed. It was thus implicit in the teaching of E2 that all counters had to be initialised before a new cycle, ie a new sensing period, was started. To a person skilled in the art, it was obvious to reset all counters as soon as a sense period ended, ie "upon diagnosis of a cardiac event". Hence, the subject-matter of claim 1 according to the first auxiliary request did not satisfy the requirements of Article 56 EPC.

Claim 1 according to the respondent's **second auxiliary request** further specified that counters simultaneously maintained cumulative counts. The teaching of E2 contained clear hints that would lead a person skilled in the art to the claimed subject-matter. Hence, claim 1 of the second auxiliary request did not involve an inventive step.

X. The respondent argued essentially as follows:

The device according to E2 comprised counters for counting heartbeat intervals which were essentially different from the storage bins referred to in the contested patent. The counters were not associated to well-defined cardiac rhythm bands and were used in the context of a system which based a diagnosis on the simultaneous application of different criteria combined into Boolean expressions. According to the contested patent, however, the diagnosis of a certain cardiac

rhythm was simply determined by the first bin to reach its predetermined count limit. In other words, the claimed invention relied on a binning technique which allowed a diagnosis to be made merely on the basis of a "first past the post" counting system. Hence, the subject-matter of claim 1 was new with respect to the closest prior art E2.

As to claim 1 of the **first auxiliary request**, E2 neither disclosed nor suggested the possibility of initialising storage bins for binning heartbeat intervals upon diagnosis of a cardiac rhythm band. Moreover, the simultaneous application of some of the criteria for diagnosing tachyarrhythmias referred to in E2 would not be possible if all storage bins had to be initialised at the same time. Since the skilled person would have had no reason to modify the teaching of E2 in such a way as to arrive at the claimed invention, the subject-matter of claim 1 met the requirements of Article 56 EPC.

The criteria specified in E2 were not compatible with the use of storage bins which simultaneously maintained cumulative counts between each diagnosis event, as specified in claim 1 according to the **second auxiliary request**. Hence, the subject-matter of this claim involved an inventive step within the meaning of Article 56 EPC.

## **Reasons for the Decision**

1. The appeal is admissible.

### **Main request**



*Interpretation of claim 1*

- 2.1 Claim 1 of the contested patent relates to an implantable cardiac pulse generator comprising:
- (a) means for sensing a patient's heartbeat;
  - (b) means for determining the intervals between heartbeats;
  - (c1) storage means including a plurality of storage count bins
  - (c2) each of said storage count bins corresponding to a different cardiac rhythm band;
  - (d) means for assigning a count limit to each storage bin;
  - (e) means for detecting when a first bin reaches its count limit;
  - (f) means for providing a diagnosis of the patient's cardiac rhythm that is responsive to the first bin to reach its count limit;
  - (g) means for initialising said storage bins;
  - (h) means for changing the count of the storage bin corresponding to the cardiac rhythm band of the determined heartbeat interval.
- 2.2 According to the respondent, the combination of features (a) to (h) recited in claim 1 defines a "first past the post" binning system, in which a diagnosis of

cardiac rhythm results from the first "storage count bin" to reach a predetermined count of heartbeat intervals. Such a system is particularly well-suited for the diagnosis of a cardiac rhythm comprising a combination of heartbeat intervals, ie a rhythm which oscillates around a border between two tachyarrhythmias (see patent specification page 2, lines 12 to 14).

- 2.3 However, since "storage count bins" are essentially counters, the Board finds that the wording of claim 1 covers also a cardiac pulse generator comprising a plurality of counters, each associated with a certain cardiac rhythm band, for counting a predetermined number of consecutive or **not** consecutive heartbeat intervals falling within corresponding rhythm bands during an **unspecified** time interval, whereby a tachyarrhythmia diagnosis is made on the basis of the first counter to reach its predetermined count.

*Novelty*

- 3.1 E2 teaches to divide the heart rate spectrum into a multiplicity of contiguous heart rate ranges comprising the sinus rhythm at the lower end of the spectrum and progressively higher rate ranges associated with ventricular tachycardia (VT) (column 7, lines 25 to 36). One of the problems addressed in this document consists in classifying a detected arrhythmia in one of the designated arrhythmia regions so as to select the appropriate therapy programmed by the physician.
- 3.2 It is observed in E2 (column 14, lines 47 to 53) that, although the partitioning of the heart rate spectrum into arrhythmia classes in itself provides a foundation for an arrhythmia detection technique, it is desirable

to obtain additional information beyond the rate boundaries of these classes in order to classify the arrhythmia more reliably. Thus, E2 specifies some algorithms for distinguishing between arrhythmias which should be treated by the device and those which should be left untreated. Some of these criteria are defined as "sudden onset", "rate stability", and "sustained high rate".

- 3.3 In column 17, lines 11 to 31, however, E2 teaches to reduce the number of detection criteria to be used in the detection following initial screening of a ventricular tachycardia (VT). In particular, if any criterion is no longer applicable as a result of the continuation of the initially detected arrhythmia episode, that criterion is no longer used in redetection. Hence, according to E2, **high rate** ("HR") and **high rate and rate stability** ("HR AND RS") are the only remaining tests suitable for redetection. As specified in column 15, lines 25 to 30, the HR criterion is satisfied if the patient's heart rate exceeds 100 bpm over the course of at least six consecutive beats. The RS criterion is met if the patient's heart rate exceeds the specified base rate over a predetermined number n of consecutive beats and the heart rate does not vary by more than a specified delta rate over those n consecutive beats (column 15, lines 40 to 46).

The HR criterion and the RS criterion are used in both initial screening and redetection, and each is assigned two separately programmable n's for initial detection and redetection, since shorter run lengths suffice for the purpose of redetection (column 17, lines 32 to 47).

Hence, the device shown in E2 comprises counters (or "bins" according to the wording used in the contested patent) for counting predetermined run lengths of heartbeats.

- 3.4 It is further specified in E2 (see column 17, lines 50 to 55) that the more stringent redetection algorithm "HR AND RS" is assigned to the tachycardia class TACH-1, and the more relaxed redetection test "HR" is assigned to each of the TACH-2 and TACH-3. This implies that there are at least three heart rhythm bands (*i.e.* TACH-1, TACH-2 and TACH-3) associated with corresponding counters (*ie* storage bins) for counting **consecutive** heartbeat intervals. When a bin is full, *i.e.* when a predetermined number of consecutive heartbeats is counted within one of the cardiac rhythm bands TACH-1, TACH-2 and TACH-3, a corresponding tachycardia diagnosis is made.

Thus, as far as this particular mode of operation is concerned, the device according to E2 delivers a diagnosis on the basis of a "first past the post" binning system, in the sense that the diagnosis depends on the first "HR" counter to reach a predetermined count of **consecutive** heartbeat intervals.

- 3.5 Furthermore, E2 teaches to use two different criteria to detect fibrillation (FIB). One of the two is termed "fibrillation rate" ("FR"), and is somewhat analogous to the "HR" criterion for tachycardia detection, in the sense that a run length of n consecutive intervals must occur at a rate exceeding a predetermined rate, in the particular case, the rate at the upper boundary of the region of ventricular tachycardia (VT).

The second criterion is termed "F x/y" and specifies that x fibrillation rate intervals must occur within y consecutive intervals.

After detection of an arrhythmia in one of the TACH or FIB classes and, in response, delivery of the prescribed therapy, reversion to the sinus rate is determined on the basis of the "sinus x/y" criterion, which consists in counting x intervals at sinus rhythm out of any y consecutive intervals.

Also the implementation of the "F x/y" and "sinus x/y" criteria requires "storage bins" for counting a predetermined number x of heartbeat intervals, means for detecting when a bin reaches its count limit x and means for delivering a corresponding diagnosis.

3.6 In summary, E2 relates to a cardiac pulse generator which relies on the application of different criteria to provide a diagnosis of the patient's cardiac rhythm. In some cases, however, the diagnosis is essentially based on the counting of a predetermined number of heartbeat intervals falling within one of several predetermined cardiac rhythm bands, as recited in claim 1 of the contested patent.

3.7 Since the device shown in E2 falls within the terms of claim 1 of the main request, the subject-matter of this claim is not new within the meaning of Article 54 EPC.

***First auxiliary request***

*Novelty*

4.1 Claim 1 according to the first auxiliary request

differs from claim 1 according to the main request in that the storage bins are initialised "upon diagnosis of a cardiac rhythm".

4.2 E2 does not explicitly teach to initialise all the counters of heartbeat intervals when diagnosis of a cardiac rhythm is made.

4.3 Hence, the subject-matter of claim 1 according to the first auxiliary request is new within the meaning of Article 54 EPC.

*Inventive step*

5.1 As pointed out above, E2 teaches, *inter alia*, to count a predetermined number of **consecutive** heartbeat intervals, or a predetermined number of heartbeat intervals within a predetermined number of **consecutive** time intervals (see "F x/y" or "sinus x/y" criteria), to make a diagnosis of the patient's cardiac rhythm. As illustrated in Figure 5 of E2, the device operates cyclically. During a "sense time", heartbeat intervals are monitored and, when a tachycardia (*ie* a "sense event") is detected, therapy is delivered. At the end of the cycle, "miscellaneous initialization chores" are performed before the next cycle starts.

5.2 According to the appellant, it is implicit that, at the beginning of a cycle in which the cardiac rhythm is to be monitored, all counters involved in such monitoring have to be ready to count heartbeat intervals, *ie* they have to be in the initialised state.

5.3 In the respondent 's view, however, nothing in E2 suggests that the "F x/y" and the "sinus x/y" counters

should be reset after reaching their predetermined count  $x$ . On the contrary, if the persistence of fibrillation or stable reversion to the sinus rhythm were to be monitored, the counters would not be reset after the first diagnosis was made but would go on counting  $x$  heartbeat intervals within a shifting time window consisting of  $y$  consecutive intervals.

The respondent further argued that the simultaneous use of the "F  $x/y$ " and "sinus  $x/y$ " criteria excluded the possibility of initialising both counters together because, in the case of a heartbeat interval varying between the sinus range and the fibrillation range, the skilled person would avoid resetting the sinus counter after a diagnosis of fibrillation in order to determine as soon as possible when the heart resumed its normal sinus rhythm.

- 5.4 The Board finds that the continuous operation of the "sinus  $x/y$ " counter during and immediately after a detection of fibrillation suggested by the respondent does not correspond to the explicit teaching of E2. In fact, the latter specifies that after detection of an arrhythmia in one of the TACH or FIB classes, and in response, the delivery of the prescribed therapy sequence (modified by any selected therapy control option), the implanted stimulator must assess whether sinus rhythm has been reestablished (see E2, column 19, lines 52 to 57). Since this assessment follows a therapy, and consequently a diagnosis based on the F  $x/y$  criterion, "F  $x/y$ " and the "sinus  $x/y$  counters" should not operate simultaneously within the same sensing cycle (cf E2, Figure 5).

Hence, E2 does not exclude the possibility that all the

counters of heartbeat intervals may be initialised upon diagnosis of a cardiac rhythm. In fact, resetting of all counters involved in the detection of tachyarrhythmias may occur at any time between the delivery of a diagnosis and the start of the next monitoring cycle.

5.5 According to the cyclical mode of operation shown in Figure 5 of E2, a "sense time" is concluded with a "sense event" followed by an appropriate therapy. Since the counters have to be initialised before a sense time starts, they should be reset at some time between the occurrence of a "sense event" (*ie* the delivery of a diagnosis) and the beginning of the following "sense time". In the opinion of the Board, it would be obvious to a person skilled in the art to consider the possibility of using the occurrence of a "sense event" for resetting all the counters required for the next counting period, since such "sense event" marks the end of the counting period not just for the counter delivering the diagnosis but for all the other counters involved in the determination of a diagnosis.

5.6 Hence, the Board finds that it would be obvious to a person skilled in the art starting from E2 to arrive at a cardiac pulse generator falling within the terms of claim 1 of the first auxiliary request and that, therefore, the subject-matter of this claim is not inventive within the meaning of Article 56 EPC.

### ***Second auxiliary request***

#### *Admissibility*

6.1 Claim 1 according to the second auxiliary request is based on claim 1 of the patent in suit amended to



recite:

*"means (90) for initialising said plurality of storage bins upon said diagnosis of a cardiac rhythm", and*

*"the plurality of storage bins simultaneously maintaining cumulative counts corresponding to each of the different cardiac rhythm bands between each diagnosis event".*

6.2 These amendments and further editorial amendments to some dependent claims and to the description are supported by the application as originally filed and thus do not give rise to any objections under Article 123 (2) EPC. It is also undisputed that such amendments do not extend the protection conferred by the claim as granted and that, therefore, they are admissible under Article 123(3) EPC.

7.1 In the course of the oral proceedings, the appellant objected for the first time that the following feature:

*"means for changing the count of the storage bins corresponding to the cardiac rhythm band of the determined heartbeat intervals"*

was not clearly supported by the invention as set out in the contested patent, because it meant that the selection of the storage bin was made on the basis of the cardiac rhythm band of "the determined heartbeat interval", ie of the interval between successive heartbeats. However, the preferred embodiment of the contested patent showed that the choice of where to bin a heartbeat interval depended essentially on the average of a predetermined number of sensed heartbeat

intervals (see page 5, line 41 to page 6, line 44).

- 7.2 The Board acknowledges that "determined heartbeat interval" could indeed be interpreted as meaning only the interval between two sensed heartbeats. It is, however, clear from the description of the contested patent that this wording is supposed to define not only a heartbeat interval but also an average of intervals and a combination of both.
- 7.3 Hence, the Board accepts the respondent's interpretation of the claim, whereby "determined heartbeat intervals" relates to sensed heartbeat intervals, an average of a predetermined number of heartbeat intervals and their combination.

*Novelty*

8. Novelty of the subject-matter of claim 1 according to the second auxiliary request has not been contested by the appellant. The Boards sees no reason to consider this matter further.

*Inventive step*

- 9.1 The features which distinguish claim 1 of the second auxiliary request from claim 1 of the patent as granted define an essential aspect of the invention which consists in operating all storage bins simultaneously and in maintaining the corresponding cumulative counts until one storage bin reaches its count limit. In the opinion of the Board, these features specify the "first past the post" binning system for diagnosis of a cardiac rhythm which constitutes the gist of the present invention.

9.2 According to E2, the diagnosis of a cardiac rhythm TACH-1, TACH-2 or TACH-3 can be made by determining a run length n of heartbeat intervals falling in the corresponding bands. This implies that the counters are reset when the predetermined count n is reached or when a certain run length of heartbeat intervals in a certain range is interrupted by a heartbeat interval falling outside that range. Thus, this particular mode of operation presupposes that the counters do **not** maintain "simultaneous consecutive counts between each diagnosis".

Furthermore, E2 (column 19, lines 9 to 27) teaches to "bias the detection in favour of VF and away from a TACH 3 VT" by means of the following rules:

- (1) a cardiac cycle in the TACH-3 region is completely disregarded by the FR and F x/y criteria;
- (2) if the HR count is greater than 0 and a cardiac cycle is in the FIB region, than 1 is **subtracted** from the HR counter

The reduction of the HR count when the cardiac cycle is predominantly in the FIB region tends to suppress (or delay) the detection of TACH-3 ventricular tachycardia when the cardiac rate swings back into that region.

9.3 Hence, E2 teaches away from the use of counters which can simultaneously maintain cumulative counts.

9.4 In the absence of any citation suggesting the diagnosis of a cardiac rhythm by means of a plurality of storage bins capable of **simultaneously maintaining cumulative**

**counts** of heartbeat intervals, the Board considers that it would not be obvious to a person skilled in the art to arrive at a cardiac pulse generator falling within the terms of claim 1 of the second auxiliary request. Hence, the subject-matter of this claim involves an inventive step within the meaning of Article 56 EPC.

9.5 Since claims 2 to 6 are dependent on claim 1, claims 7 and 8 relate to a cardiac therapy device comprising the implantable cardiac pulse generator according to claim 1 and claims 9 and 10 are dependent on claim 8, their subject-matters also comply with Article 56 EPC.

10. For the above reasons, the Board comes to the conclusion that the respondent's **second auxiliary request** is allowable and that the patent can be maintained on the basis thereof. Consequently, there is no need to consider the respondent's remaining auxiliary requests.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the following documents according to the respondent's **second auxiliary request:**

**Claims:** 1 to 10 filed in the oral proceedings held on 6 November 2002;

**Description:** pages 2 and 4 filed in the oral proceedings,  
pages 3 and 5 to 7 as granted;

**Figures:** 1 to 5 as granted.

The Registrar:

The Chairman:

R. Schumacher

G. Davies