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**Datasheet for the decision
of 19 May 2010**

Case Number: T 0598/07 - 3.4.01
Application Number: 96929409.9
Publication Number: 0850016
IPC: A61B 5/0472, G06F 19/00
Language of the proceedings: EN

Title of invention:
Heart monitoring apparatus and method

Patentee:
Cardionetics Limited

Opponent:
BIOTRONIK

Headword:
-

Relevant legal provisions:
EPC Art. 123(3), 123(2)

Relevant legal provisions (EPC 1973):
EPC Art. 54, 56, 84

Keyword:
"Extension of protection (no)"
"Added subject-matter (no)"
"Novelty (yes)"
"Inventive step (yes)"
"Clarity (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 0598/07 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 19 May 2010

Appellant: Cardionetics Limited
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 16 February 2007
revoking European patent No. 0850016 pursuant
to Article 102(1) EPC 1973.

Composition of the Board:

Chairman: B. Schachenmann
Members: P. Fontenay
H. Wolfrum

Summary of Facts and Submissions

I. The appeal lies from the decision of the opposition division to revoke European patent No. EP-B-850016. The decision was based on the ground of lack of inventive step (Article 56 EPC 1973) of the subject-matter of the independent claims of the main request and auxiliary request then on file. It was announced during the oral proceedings before the opposition division on 21 September 2006 and notified to the parties on 16 February 2007.

In the reasons for its decision the opposition division held that the subject-matter of the independent claims of the main request was obvious when considering DE-A-39 12 028 (E3) as closest prior art in view of document DE-A-44 10 508 (E9). The opposition division also held that a similar conclusion could be reached when considering EP-A-487 429 (E6a) as closest prior art when combined with document E9.

Concerning the auxiliary request, the opposition division concluded that the subject-matter of the independent claims was also obvious in view of a combination of document E6a with E9.

II. The appellant (the patentee) filed a notice of appeal against this decision by facsimile dated 11 April 2007 and paid the prescribed appeal fee on the same day. Cancellation of the decision in full was requested.

In the written statement setting out the grounds of appeal filed on 22 June 2007, the appellant requested that the patent be maintained in an amended form on the

basis of amended sets of claims annexed to the statement of grounds according to a new main request or, alternatively, according to a first, second or third auxiliary request.

Claims 1-64 of the first and second auxiliary requests corresponded, respectively, to claims 1-64 and 65-128 of the main request.

- III. In a facsimile dated 9 November 2007, the representative of the respondent (Opponent) indicated that it was not intended to reply to the statement of grounds of appeal.
- IV. At the request of the appellant, a summons to attend oral proceedings, scheduled to take place on 2 December 2009, was issued.

On 7 September 2009, in view of the oral proceedings to be held, the Board issued a communication pursuant to Article 15(1) Rules of Procedure of the Boards of Appeal (RPBA) expressing its provisional opinion on points raised by the appellant with regard to the set of claims then on file. The attention of the appellant was drawn particularly to the fact that the modified wording of the claims was possibly infringing the requirements of Article 123(2) EPC.

Concerning, more specifically, the issue of inventive step, the provisional analysis of the prior art carried out by the Board was consistent with the conclusion reached by the opposition division in its decision to revoke the patent. In particular, the Board likewise held that documents E3 and E6a appeared to be essential

when deciding on the inventive merits of the claimed subject-matter. With particular regard to the second auxiliary request, the Board pointed out that, in its provisional opinion, document E6a was to be considered as closest prior art.

V. With letter dated 27 October 2009, the appellant filed a modified version of each of the main request, the first auxiliary request and the third auxiliary request. These requests were amended, taking into account the comments made by the Board regarding the issue of added subject-matter. Besides, the appellant provided additional arguments which, in its view, supported the reference in the claims to the notion of "n dimensional volumes" previously objected to by the Board.

VI. As announced by a notice dated 2 September 2009, the respondent was not represented at the oral proceedings which, thus, took place in the sole presence of the appellant on 2 December 2009.

During the oral proceedings, the appellant requested as its only request that the patent be maintained according to a modified set of claims 1-50 and amended description pages. This request was, in essence, based on the previous second auxiliary request filed with the statement of grounds.

After closure of the debate and deliberation by the Board, the Chairman announced that the appeal proceedings would be continued in writing based on the appellant's request filed in the oral proceedings.

VII. The wording of claim 1 reads:

"1. Heart monitoring apparatus comprising:

input means (1) for receiving an electrocardiograph signal from a patient during a monitoring phase;

preprocessing means (10) for processing said electrocardiograph signal to suppress the noise and to analyse the shape of each pulse of said electrocardiograph signal to obtain a plurality n of values representative of the shape of each pulse of said electrocardiograph signal;

storage means for storing a first set of n dimensional reference vectors for the identification of distinctive irregular heartbeats which are spurious with regard to monitoring heart conditions, and a second set of n dimensional reference vectors for monitoring regular heartbeats, each said n dimensional reference vector comprising a plurality n of values representative of the shape of an irregular heartbeat or a regular heartbeat respectively; and

Kohonen neural network means (11) for, during the monitoring phase, initially reading the stored first set of reference vectors defining an n dimensional Kohonen feature map, defining an irregular heartbeat n dimensional volume in n dimensional space using the first set of reference vectors and threshold ranges around the first set of reference vectors, receiving said plurality n of values for each pulse, forming an n dimensional vector from said plurality n of values for each pulse, and comparing the formed n dimensional vector with the irregular heartbeat n dimensional volume to determine if said n dimensional vector lies within or outside said irregular heartbeat n

dimensional volume to identify distinctive irregular heartbeats; and subsequently reading the stored second set of reference vectors defining an n dimensional Kohonen feature map, defining a regular heartbeat n dimensional volume using the second set of reference vectors and threshold ranges around the second set of reference vectors, comparing the n dimensional vector formed from a regular heartbeat which does not include a distinctive irregular heartbeat with the regular heartbeat n dimensional volume, and outputting an indication if it is determined that said n dimensional vector formed from said regular heartbeat is within or outside said regular heartbeat n dimensional volume."

The wording of independent claim 28 reads:

"28. A heart monitoring method comprising the steps of:
receiving an electrocardiograph signal from a patient during a monitoring phase;
preprocessing the electrocardiograph signal to suppress the noise and to analyse the shape of each pulse of said electrocardiograph signal to obtain a plurality n of values representative of the shape of each pulse of said electrocardiograph signal; and
using Kohonen neural network means (11) during the monitoring phase to initially read a stored first set of n dimensional reference vectors defining an n dimensional Kohonen feature map for the identification of distinctive irregular heartbeats which are spurious with regard to monitoring heart conditions, each said n dimensional reference vector comprising a plurality n of values representative of the shape of each pulse of a distinctive irregular heartbeat, to define an irregular heartbeat n dimensional volume in n dimensional space using the first set of reference

vectors and threshold ranges around the first set of reference vectors, to receive said plurality n of values for each pulse, to form an n dimensional vector from said plurality n of values for each pulse, and to compare the formed n dimensional vector with the irregular heartbeat n dimensional volume to determine if said n dimensional vector lies within or outside said irregular heartbeat n dimensional volume to identify the distinctive irregular heartbeats; and subsequently to read a stored second set of n dimensional reference vectors defining an n dimensional Kohonen feature map for monitoring regular heartbeats, each said n dimensional reference vector comprising a plurality n of values representative of the shape of each pulse of a regular heartbeat, to define a regular heartbeat n dimensional volume using the second set of reference vectors and threshold ranges around the second set of reference vectors, to compare the n dimensional vector formed from a regular heartbeat which does not include a distinctive irregular heartbeat with said regular heartbeat n dimensional volume, and to output an indication if it is determined that said n dimensional vector formed from said regular heartbeat is within or outside said regular heartbeat n dimensional volume."

Claims 2 to 27 and 29 to 50 depend, respectively, on independent claims 1 and 28.

VIII. With a Board's communication dated 16 December 2009, the debate was reopened insofar as the description filed during the oral proceedings was concerned. The attention of the parties was drawn to various statements therein which, as a consequence of the

multiple amendments made to the claims during the appeal proceedings, were not consistent anymore with said claims. These inconsistencies led to some doubts as to the matter for which protection was conferred contrary to Article 84 EPC 1973.

The appellant was thus invited to file a modified version of the patent description.

By letter dated 12 February 2010, the appellant filed an amended version of the description and drawings. In particular, Figure 8 and the corresponding passages in the description had been deleted.

The parties were informed by a communication pursuant to Article 15 RPBA dated 29 March 2010, issued in view of further oral proceedings to be held in connection with this case, that the Board considered the amendments made to the description and drawings to raise new issues. It was in particular stressed that the deletion of Figure 8 and the associated passages in the description deprived some claims of their support in the description. The terminology employed throughout the description was also not consistent with the claims thus leading to further objections under Article 84 EPC 1973.

In a facsimile dated 30 April 2010, the appellant filed a modified version of the description and withdrew its previous request to amend the drawings. A clean copy of the claims agreed upon during the oral proceedings on 2 December 2009 was also filed.

In a facsimile dated 10 Mai 2010 the respondent indicated that it did not intend to be represented at the oral proceedings, which were accordingly cancelled.

- IX. In the context of this decision, reference is made to the provisions of the EPC 2000, which entered into force as of 13 December 2007, unless the former provisions of the EPC 1973 still apply to pending applications. In this latter case, the citation of Articles or Rules is followed by the indication "1973" (cf. EPC, page 4, "citation practice").

Reasons for the Decision

1. The appeal is admissible.
2. *Extension of protection (Article 123(3) EPC)*

Independent claims 1 and 28 differ from granted claims 1 and 41, essentially, in that the claimed subject-matter has been further limited so as to precisely define the processing carried out by the neural network and by specifying that a Kohonen neural network is required for such processing. More specifically, independent claims 1 and 28 recite that the n-dimensional vectors representative of the monitored ECG are compared with a first n dimensional volume representative of irregular heartbeats, which are spurious with regard to monitoring heart conditions, and subsequently with a second n dimensional volume representative of regular heartbeats.

These amendments lead to a restriction of the extent of protection and therefore comply with the requirements of Article 123(3) EPC.

3. *Added subject-matter (Article 123(2) EPC)*

Independent claim 1 finds its basis in a combination of original claims 1 and 21. Similarly, independent claim 28 derives, primarily, from a combination of original claims 39 and 56.

Although the current independent claims do not explicitly recite the features of original claims 16 and 53 on which original claims 21 and 56 respectively depended, according to which the distinctive irregular heartbeats were removed from the electrocardiogram signal before subsequently performing the comparison with the regular heartbeat n dimensional volume, the Board concluded that the amendments were allowable. In the Board's judgment, the reference to "the n dimensional vector formed from a regular heartbeat which does not include the distinctive irregular heartbeats" in current independent claims 1 and 28 indeed implies that a removal of these distinctive heartbeats must have been carried out in a previous step.

The reference to an n dimensional volume may be found in original claim 72. This concept of n dimensional volumes is further supported by the notion of "regions" in a multi-dimensional space discussed on pages 23 to 27 of the published application in connection with Figures 9 to 11 when addressing the specific situation of a two dimensional pattern.

The Board is thus satisfied that the amendments made comply with the requirements of Article 123(2) EPC.

4. *Novelty - Inventive step*

4.1 *Prior art*

During the appeal proceedings, the following documents were taken into account:

- E1: US-A-5 271 411;
- E2: US-A-3 524 442;
- E3: DE-A-39 12 028;
- E4: US-A-5 348 020;
- E5: Biomedizinische Technik, Vol. 18, No 6, pages 226-229; K. Meyer-Waarden et al. "An Arrhythmia-Anomalous Beat Monitoring System";
- E6a: EP-A-0 487 429;
- E7: EP-A-0 348 271;
- E8: US-A-5 280 792;
- E9: DE-A-44 10 508;
- E10: Rojas, "Theorie der Neuronalen Netze - Eine systematische Einführung", Berlin, Springer, 1991, pages 339-359.

4.2 *Novelty - Article 54 EPC 1973*

- 4.2.1 Document E6a discloses a heart monitoring apparatus with input means (7, 8, 9) for receiving an electrocardiograph signal from a patient during a monitoring phase. Preprocessing means are foreseen for processing said electrocardiograph signal to suppress the noise (cf. column 2, lines 42 - 49). The preprocessing means further carry out feature

extraction in order to extract important features of the shape of a sequence of pulses of said electrocardiograph signal to obtain a plurality n of values representative of the shape of said sequence of pulses of said electrocardiograph signal (cf. column 3, lines 15-20; column 5, lines 4-19, 26-36).

Storage means are provided in E6a for storing a plurality m of n dimensional reference vectors, each said n dimensional reference vector comprising n values representative of the shape of reference sequences (cf. column 3, lines 21-25; column 3, line 50 - column 4, line 5).

During the monitoring phase, an n dimensional vector is formed from n values representative of a sequence of pulses received wherein said vector is then compared with an n dimensional volume defined by the plurality of reference vectors and threshold ranges around said vectors, to determine the proximity of said formed vector to said n dimensional volume (cf. column 10, lines 12-17; 22-38). An indication as to whether said n dimensional vector lies within or outside said n dimensional volume is also provided (cf. column 10, lines 17-21).

According to a first embodiment, E6a suggests to compare the thus obtained n dimensional vector with an n dimensional volume defined by the plurality of reference vectors representative of abnormal (irregular) data. Alternatively, according to a second embodiment, said comparison is carried out with reference vectors representative of regular heartbeats (cf. column 10, line 51 - column 11, line 17). Moreover, as specified in column 11, lines 18-20, both

embodiments can be combined in the same device, as required in present claims 1 and 28.

The subject-matter of claims 1 and 28 differs therefore from the apparatus and method disclosed in E6a, *inter alia*, in that the plurality n of values to be obtained is representative of the shape of each pulse of the electrocardiogram and not of a sequence of pulses as is the case in E6a (cf. column 4, lines 17-37) and in that Kohonen networks are utilised.

4.2.2 Document E3 discloses a heart monitoring apparatus comprising input means (4) for receiving an electrocardiograph signal from a patient (2) during a monitoring phase and preprocessing means for processing said electrocardiograph signal. The preprocessing means suppress the noise (cf. column 3, lines 37-42) and carry out feature extraction to extract important features of the shape of each pulse of said electrocardiograph signal (cf. column 4, lines 15-67) to obtain four values representative of this shape. Storage means (26) are also provided in E3 for storing a plurality of four-dimensional reference vectors, each said four-dimensional reference vector comprising four values representative of the shape of a reference pulse (cf. column 5, lines 11-14; column 6, lines 12-56).

During the monitoring phase, a four-dimensional vector is formed from four values representative of the shape of each pulse received. This vector is then compared with a four-dimensional volume defined by the plurality of reference vectors and threshold ranges around said vectors to determine the proximity of said formed vector to said four-dimensional volume. In addition, an

indication as to whether said four-dimensional vector lies within or outside said four-dimensional volume is generated (cf. column 5, lines 27-40; column 5, line 56 - column 6, line 11).

The subject-matter of claims 1 and 28 is thus distinguished from this known apparatus and method in that:

- the formed n dimensional (four-dimensional) vector representative of each pulse is first compared with a irregular heartbeat n dimensional volume and subsequently with a regular heartbeat n dimensional volume;
- data processing is carried out by Kohonen neural network means.

4.2.3 Documents E1, E2, E5, E7 and E8 relate to conventional monitoring systems and methods. These prior publications do not contain any information relating to the use of Kohonen networks. Moreover, none of them discloses means to compare input vectors with two sets of reference vectors so as to first get rid of vectors indicative of spurious irregular beats before the second comparison is carried out.

Document E4 discloses an ECG monitoring system in which vectors representative of sequences of pulses are obtained. These vectors are, however, not compared with reference vectors. There is also no indication in E4 to use Kohonen networks.

Documents E9 and E10 have been cited by the opponent to illustrate specific aspects of the invention. They refer, respectively, to the use of Kohonen networks

when monitoring various parameters of a patient (E9) or, more generally, to the theory underlying Kohonen networks (E10).

4.2.4 None of the documents E1 to E10 thus anticipates the subject-matter of independent claims 1 and 28 which, therefore, meets the requirements of Article 54 EPC 1973 as to novelty.

4.3 *Inventive step - Article 56 EPC 1973*

4.3.1 As emphasized by the appellant during the oral proceedings on 2 December 2009, the purpose of the system and technique disclosed in document E6a is to identify a pattern of behaviour over time. To achieve this, the system disclosed in E6a consistently relies in its various embodiments on the analysis of a succession of pulses, the number of which may vary from 6 cycles to some millions of cycles (cf. E6a, column 4, lines 17-37). It does not determine, as such, values or a vector representative of the shape of each pulse of the electrocardiograph signal as actually required by the wording of independent claims 1 and 28 on file.

In the Board's judgement, although E6a suggests a two-step analysis of the obtained electrocardiograph signals by combining two embodiments, it does not qualify as closest prior art. It is established jurisprudence of the Board's of appeal that the closest prior art must share a common purpose with the claimed invention. This implies, in the present situation, that a skilled person working on the elaboration of a system and method the primary purpose of which is to monitor each single pulse of the electrocardiograph signal

would not start from a teaching which, on the contrary, only delivers values representative of a sequence of pulses in which the information pertaining to an individual pulse is actually lost.

For these reasons and since document E3 does disclose the step of comparing the waveshape for a single pulse with the reference waveshapes for reference pulses and shares multiple other features with the claimed invention (cf. above, section "Novelty"), its teaching is considered to be more appropriate as a starting point when deciding on the inventive merits of the claimed invention.

Documents E1, E2, E4, E5, E7 and E8 also relate to the field of ECG monitoring, but are farther away from the claimed inventions. Even though the use of Kohonen Networks is mentioned in passing in relation with electrocardiograms in document E9, E9 does not contain any details as to the type of analysis to be actually carried out. The same applies to E10. Consequently, none of documents E1, E2, E4, E5 and E7 to E10 appears to constitute a suitable starting point when deciding on the obviousness of the claimed invention.

- 4.3.2 As observed above under section "novelty", the claimed apparatus differs from the apparatus described in document E3 in that:
- the n dimensional vector representative of each pulse is first compared with the irregular heartbeat n dimensional volume, to identify distinctive irregular beats which are spurious with regard to monitoring heart conditions, and subsequently with a regular heartbeat n dimensional volume;

- data processing is carried out by Kohonen neural network means.

The technical effect obtained by these distinguishing features is to allow the second comparison with the regular heartbeat n dimensional volume to be carried out only for n dimensional vectors formed from a regular heartbeat which does not include a distinctive irregular heartbeat.

This configuration permits to improve the signal to noise ratio and thereby reduce the number of false identifications of novel electrocardiograph signals, as acknowledged on page 8, lines 13-18 of the original application, as published under the PCT.

Although document E6a does suggest comparing vectors representative of series of pulses in electrocardiograph signals with n dimensional volumes indicative of regular and irregular heartbeats, the Board is convinced that it does not render the claimed subject-matter obvious. To reach its conclusion, the Board notes that the irregular n dimensional volume defined in E6a is representative of specific heart conditions, such as e.g. bradycardia, tachycardia, fibrillation, which, incidentally, in the present application are defined as "regular" abnormal pulses (cf. dependent claim 27). There is accordingly no teaching in E6a to first identify distinctive irregular pulses which are spurious with regard to monitoring the heart condition. The problem associated with false identifications is also not addressed in E6a. Therefore, since this prior publication neither addresses the objective problem underlying the present

invention nor discloses the claimed solution, its teaching does not render the apparatus of claim 1 and method of claim 28 obvious when combined with that of document E3.

In conclusion, the subject-matter of claim 1 is considered to be inventive in the sense of Article 56 EPC 1973. The same conclusion applies *mutatis mutandis* to the subject-matter of independent claim 28.

5. *Exceptions to patentability - Article 53(c) EPC*

Since none of the method claims 28 to 50 includes the step relating to the diagnosis for curative purposes *stricto sensu* representing the deductive medical or veterinary decision phase, the Board is satisfied that the current method claims do not fall under the exclusion provisions of Article 53(c) EPC (former Article 52(4) EPC 1973), (cf. G 1/04, headnote I, point 6.2.4). In fact, the Board notes that independent claim 28 merely provides an indication as to whether the n dimensional vector formed from a regular heartbeat is within or outside the regular heartbeat n dimensional volume. The fact that, according to the description, the notion of regular heartbeats encompasses regular normal heartbeats, reflecting normal heart conditions, or, alternatively, regular abnormal heartbeats indicative of unhealthy heart conditions, does not affect this finding since the claim's wording does not actually and does not need to incorporate the deductive decision phase of establishing a diagnosis for curative purposes. The method of claim 28 may, for example, be used to activate an alarm in response to the output indication

(cf. claim 41). As disclosed in the original published description (cf. page 10, lines 10-17), this measure would allow a subsequent analysis of the electrocardiograph signal by a suitably trained person. The fact that according to some examples of the invention an audible or visual indication of the specific heart condition may be provided by the system (cf. paragraphs [0061] to [0063] of the patent description), does also not affect this finding, insofar as none of the method claims reproduces this limitation.

6. *Clarity - essential features*

Since it cannot be inferred from the original description that the diagnosis step is an essential feature of the claimed method, the Board is satisfied that the requirements of Article 84 EPC 1973 are met by independent claim 28.

7. The amended description meets the requirements of the EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the following documents:
 - Claims 1 to 50 filed on 30 April 2010;
 - Description pages 1-25 filed on 30 April 2010;
 - Figures 1 to 24 as published in the patent specification.

The Registrar

The Chairman

R. Schumacher

B. Schachenmann