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Datasheet for the decision of 21 November 2012

Case Number: T 0765/09 - 3.2.02

Application Number: 05724861.9

Publication Number: 1729631

IPC: A61B 5/00

Language of the proceedings: EN

Title of invention:
Selection of ensemble averaging weights for a pulse oximeter based on signal quality metrics

Applicant:
Nellcor Puritan Bennett LLC

Headword:
-

Relevant legal provisions:
EPC Art. 54, 123(2), 84

Keyword:
"Novelty (no) - auxiliary request 1"
"Added subject-matter (no)"
"Clarity (yes)"
"Novelty (yes) - auxiliary request 3"

Decisions cited:
-

Catchword:
-

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Case Number: T 0765/09 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 21 November 2012

Appellant: (Applicant)
Nellcor Puritan Bennett LLC
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Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 14 November 2008 refusing European patent application No. 05724861.9 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: E. Dufrasne
Members: M. Stern
C. Körber

Summary of Facts and Submissions

I. The appeal is against the decision of the Examining Division, dispatched on 14 November 2008, refusing European application No. 05 724 861.9 inter alia for lack of novelty in view of the following documents:

D1: US-A-2002/0 137 994
D2: US-A-4 960 126.

II. The notice of appeal was received on 14 January 2009 and the appeal fee was paid on the same day. A statement setting out the grounds of appeal was received on 13 March 2009.

III. The Board presented its provisional opinion in a communication dated 4 September 2012 raising, inter alia, objections regarding added subject-matter and novelty.

IV. Oral proceedings took place on 21 November 2012.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the auxiliary request 1 filed on 22 October 2012 or, in the alternative, on the basis of auxiliary request 3 filed during the oral proceedings, or on the basis of one of auxiliary requests 4 and 5 filed on 22 October 2012. The main request and auxiliary request 2, filed on 22 October 2012, and the request for reimbursement of the appeal fee filed on 13 March 2009, were withdrawn during the oral proceedings.

V. Claim 1 of auxiliary request 1 reads as follows:

"1. A method of ensemble averaging signals in a pulse oximeter, comprising:
receiving first and second electromagnetic radiation signals from a blood perfused tissue portion corresponding to two different wavelengths of light; and
obtaining an assessment of the signal quality of said electromagnetic signals by obtaining a measure of a degree of similarity or correlation between said first and second electromagnetic radiation signals;
selecting weights for an ensemble averager using said assessment of signal quality; and
ensemble averaging said electromagnetic signals using said ensemble averager."

VI. Independent claims 1 and 10 of auxiliary request 3 read as follows:

"1. A method of ensemble averaging signals in a pulse oximeter, comprising: receiving first and second electromagnetic radiation signals from a blood perfused tissue portion corresponding to two different wavelengths of light; normalising said electromagnetic signals to provide normalised electromagnetic signals; obtaining an assessment of the signal quality of said first and second electromagnetic signals; selecting weights for two ensemble averagers using said assessment of signal quality; ensemble averaging said first and second electromagnetic signals using one of said ensemble averagers and using the ensemble averaged first and second electromagnetic signals to determine a

pulse rate, and ensemble averaging said normalised electromagnetic signals using the other one of said two ensemble averagers and using the ensemble averaged normalised signals to determine oxygen saturation."

"10. A device for ensemble averaging signals in a pulse oximeter, comprising: means for receiving first and second electromagnetic radiation signals from a blood perfused tissue portion corresponding to two different wavelengths of light; means for normalising said electromagnetic signals to provide normalised electromagnetic signals; means for obtaining an assessment of the signal quality of said first and second electromagnetic signals; means for selecting weights for two ensemble averagers using said assessment of signal quality; one of the two ensemble averagers being provided for ensemble averaging said first and second electromagnetic signals using said weights; means for using the ensemble averaged signals from the said one of the two ensemble averagers to determine a pulse rate; the other one of the two ensemble averagers being provided for ensemble averaging said normalised electromagnetic signals, and means for using the ensemble averaged normalised signals from the said other of the two ensemble averagers to determine oxygen saturation."

Claims 2 to 9 and 11 to 18 are dependent claims.

VII. The arguments of the appellant are summarised as follows:

Claim 1 of auxiliary request 1 was novel over documents D1 and D2 since neither of these documents

disclosed selecting ensemble averaging weights using an assessment of the signal quality of the electromagnetic signals by obtaining a measure of the degree of similarity or correlation between the first and second electromagnetic radiation signals corresponding to two different wavelengths of light.

In particular, in D1, the assessment of signal quality between the red and infrared signals was performed by the adaptive comb filter 32 only for the calculation of the heart rate. The assessment of signal quality was however not used in the oxygen saturation calculator 50 comprising the Kalman averager 16, so that it was not used for the selection of weights for the Kalman averager. Furthermore, a Kalman averager was not an "ensemble averager" as claimed and would never be interpreted as such by a person skilled in the art. The term "ensemble averager" was well known in the art of statistics and could be applied to various technologies in which statistical calculations were necessary.

Independent claims 1 and 10 of auxiliary request 3 remedied all objections under Articles 123(2) and 84 EPC raised by the Board. In particular, their subject-matter allowed a more flexible and more robust weight selection methodology for ensemble averaging of signals than the one disclosed in document D2, from which the original application departed. The provision of two separate ensemble averagers for determining pulse rate and oxygen saturation, respectively, allowed a more accurate determination of these physiological parameters. The appellant agreed to the remittal of the case to the Examining Division for further prosecution.

Reasons for the Decision

1. The appeal is admissible.

2. *Auxiliary request 1*

2.1 Document D1 discloses the averaging of plethysmographic waveforms in a pulse oximeter by a processor using Kalman filter theory (Kalman cardiac gated averaging (CGA) processor 16 in Fig. 1b) which uses variable weights for different wavelengths (paragraphs [0033], [0034], [0039], [0084]). The Kalman CGA processor removes noise by performing averages over cycles of plethysmographic waveforms (last sentence of paragraph [0037]), and thus performs "ensemble averaging" as defined in claim 1.

2.2 The Kalman CGA processor (16) is moreover disclosed as a cardiac gated averaging processor (paragraph [0084]) which is triggered by an adaptive comb filter (ACF 32 in Fig. 1b). The adaptive comb filter (ACF 32) robustly tracks the heart rate through noisy environments (paragraph [0036]) by calculating, as a metric, a degree of correlation between the received red and infrared signals (see last portion of paragraph [0178] on page 13). In paragraph [0156] it is explained that noise induced by motion artifacts causes the red and infrared electromagnetic signals to become less correlated. Hence, the calculated degree of correlation of the red and infrared signals constitutes an "assessment of the signal quality of said electromagnetic signals".

Whilst this fact was not disputed by the appellant, the appellant argued during oral proceedings that the mentioned assessment of signal quality was performed by the adaptive comb filter only for the calculation of the heart rate, but not for that of the oxygen saturation, in particular not for the selection of weights for the Kalman averager.

This view is not shared by the Board, since the adaptive comb filter 32 triggers the Kalman cardiac gated averager 16 (at step 36 in Fig. 1b), whereby the weights of the Kalman averager are selected based on said assessment of signal quality performed by the adaptive comb filter. Thus the claimed step of "selecting weights for an ensemble averager using said assessment of signal quality" in a pulse oximeter is also anticipated by D1.

2.3 The Board could also not accept the appellant's assertion that the Kalman CGA in D1 could not be equated with the claimed "ensemble averager". The appellant merely asserted that the skilled person in the present field of pulse oximetry would know that this expression carried a more specific meaning, but the appellant failed to indicate what this precise difference might be, let alone to present convincing evidence of it.

Hence, based on the disclosure of the present application, in particular page 1, lines 19 to 22 (or even according to earlier document D2 from which the application departs, in particular column 9, lines 61 to 63 and feature (c) of claim 1 of D2), the Board finds that the expression "ensemble averaging" has no

further meaning than the averaging of pulse waveforms over time using weighting factors. The Kalman CGA disclosed in D1 performs such weighted averaging (paragraphs [0039], [0084]).

2.4 Consequently, the subject-matter of claim 1 of the auxiliary request 1 lacks novelty over document D1, contrary to Article 52(1) EPC in conjunction with Article 54 EPC.

3. *Auxiliary request 3*

3.1 Amended independent claims 1 and 10 of auxiliary request 3 were filed during the oral proceedings, effectively remedying objections raised by the Board concerning the requirements of Articles 123(2) and 84 EPC.

In fact, claims 1 and 10 are based on original claims 1 and 10 respectively, supplemented by the features disclosed on page 13, lines 16 to 21. These features are mainly directed to the selection of weights for two separate ensemble averagers, one of which determines pulse rate and the other determines oxygen saturation. As explained moreover on page 13, line 26 to page 14, line 2, different metrics can be chosen for each of the two ensemble averagers and can be varied to optimise the ensemble averaging for oxygen saturation or pulse rate calculations, allowing a more accurate determination of these physiological parameters.

The Board consequently finds that amended independent claims 1 and 10 of auxiliary request 3 comply with the requirements of Articles 123(2) and 84 EPC.

3.2 The aforementioned added features are moreover not disclosed in document D1 or D2, so that the subject-matter of claims 1 and 10 is novel within the meaning of Article 54 EPC over these documents.

3.3 The contribution of these features to inventive step, however, was not examined in the course of the examination proceedings. Since these features were only disclosed in the above-cited passage of the description of the application, i.e. they have no counterpart in the originally filed and searched claims, it also seems doubtful that they were adequately taken into consideration by the prior art search.

The Board therefore finds it appropriate not to conclusively decide the question of inventive step, but to remit the case to the Examining Division for continuation of the examination proceedings (Article 111(1) EPC). At oral proceedings the appellant agreed to the envisaged remittal.

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 for further prosecution.

The Registrar: The Chairman:

D. Hampe E. Dufrasne