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D E C I S I O N
of 8 March 2002

Case Number: T 0755/98 - 3.2.2

Application Number: 94929375.7

Publication Number: 0727960

IPC: A61B 5/00

Language of the proceedings: EN

Title of invention:

Pulse oximeter using a virtual trigger for heart rate synchronization

Applicant:

Nellcor Puritan Bennett Incorporated

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 84, 56

EPC R. 67

Keyword:

"Clarity (yes, after amendments)"

"Inventive step (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 0755/98 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 8 March 2002

Appellant: Nellcor Puritan Bennett Incorporated
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Representative: Hall, Robert Leonard
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 14 May 1998
refusing European patent application
No. 94 929 375.7 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noël
J. C. M. De Preter

Summary of Facts and Submissions

- I. The Examining Division refused European patent application No. 94 929 375.7 (PCT publication No. WO 95/10222) on 14 May 1998, on the grounds that the claims and the description lacked clarity (Article 84 EPC), having regards in particular to the meaning of the terms "C-lock process", "virtual trigger" and "arbitrary".

These inconsistencies resulted in that the claimed subject-matter could not be distinguished from the state of the art, if only by minor features without inventive significance (Article 56 EPC).

- II. The prior art is represented by documents:

D1: US-A-4 928 692, and

D2: EP-A1-0 442 011.

- III. The appellant lodged an appeal against this decision on 14 July 1998. Its statement of grounds was filed on 24 July 1998 along with new sets of claims and correspondingly adapted pages of the description.

The appellant put forward arguments to support the clarity of the terms used in the application, and explained the invention by comparison with the oximetry systems known from the prior art. As to the inventive step, the appellant submitted essentially that the ECG R-wave trigger used in document D1 was neither virtual nor arbitrary, and that in document D2 the optical signal itself was used as heart rate signal and not as signal received from an external and independent heart

- rate source, as it was claimed by the invention.
- IV. On 14 September 1998, the appellant presented further arguments to support a request for reimbursement of the appeal fees, based on an alleged procedural violation on behalf of the Examining Division.
- V. In a communication dated 21 November 2001 the appellant was informed that the Board would favourably consider one of the sets of claims previously submitted, provided that further amendments be made in the claims and in the description.
- VI. The appellant replied by letter of 10 January 2002, submitting a new set of claims 1 to 7 and a complete set of amended pages 1 to 22 of the description.
- VII. The appellant now requests that a patent be granted on the basis of the patent application documents filed on 10 January 2002 and the drawings (sheets 1 to 10) as published. Further, he requests that the appeal fee be reimbursed.
- VIII. Independent claims 1 (apparatus) and 6 (method) read as follows (identifying letters (a) to (f) introduced by the Board for ease of reference):

"1. Pulse oximeter signal processing apparatus comprising:

(a) means for generating a pulse oximeter signal from an optical monitor, said signal having a specific period; and

(b) means for receiving a heart rate signal from a

heart rate monitor, said heart rate signal having the same specific period;

characterised in that it further comprises

(c) means to generate a virtual trigger from said heart rate signal; and

(d) means for processing said pulse oximeter signal by averaging the signal over a plurality of periods defined by said virtual trigger; in that

(e) the phase relationship between said virtual trigger and said heart rate signal is arbitrary; and in that

(f) said virtual trigger is generated while said heart rate signal is received and for at least several periods in the event that the heart rate is not accurately updated every beat."

"6. A method of processing a pulse oximeter signal, said method comprising:

generating a pulse oximeter signal from an optical monitor, said signal having a specific period; and

receiving a heart rate signal from a heart rate monitor, said heart rate signal having the same specific period;

characterised by said method further comprising

generating a virtual trigger from said heart rate signal; and

processing said pulse oximeter signal by averaging the signal over a plurality of periods defined by said virtual trigger, in that

said virtual trigger is generated with a phase relationship to said heart rate signal which is arbitrary; and in that

said virtual trigger is generated while said heart rate signal is received and for at least several periods in the event that the heart rate is not accurately updated every beat."

Reasons for the Decision

1. The appeal is admissible.
2. *Amendments*

The invention relates to a method and an apparatus for oximeter signal processing, in accordance with the general introduction of the description. Due to narrow similarities between the features of the apparatus and those of the method, the following statements about the apparatus claim equally apply to the method claim.

The features of the independent claims are supported by the following passages of the application as filed in

the version as published under the PCT:

feature (a) is supported by page 6, lines 1 to 17 in connection with Figures 2A and 2B;

feature (b) is supported from page 6, line 36 to page 7, line 8 in connection with Figure 2B;

feature (c) is supported from page 8, line 36 to page 9, line 4 in connection with Figure 3D;

feature (d) is supported by page 8, lines 13 to 24 in connection with Figure 3D;

feature (e) is supported by page 3, lines 20 to 23 and lines 31 to 34;

feature (f) is supported from page 8, line 36 to page 9, line 15 and by page 13, lines 7 to 11 in connection with Figure 3B;

As to the dependent claims:

claim 2 is supported by page 7, lines 1 to 8 and 18 to 19 and by page 9, lines 17 to 20

claims 3 and 7 are supported by page 13, lines 19 to 23

claim 4 is supported by the text in connection with Figure 2B and 3B

claim 5 is supported by page 11, lines 22 to 24.

The description has been appropriately amended and adapted to the new filed claims.

Consequently, all the amendments made are fairly supported by the application as filed and do not extend beyond its original content, in accordance with Article 123(2) EPC.

3. *Clarity and the invention in relation to document D1*

3.1 The invention starts from document D1, which is considered as closest prior art and mentioned in the introductory part of the application as filed. There, a pulse oximeter is known for increasing the accuracy of pulse oximetry measurements obtained by red and infrared absorption characteristics of oxygen in the blood. A problem with non-invasive pulse oximeters is that the optically derived pulse rate may be subject to motion artifacts that interfere with the detection of the blood flow characteristics and, therefore, to difficulties by separating the true pulsatile component from artifact pulses.

In document D1, the Figure 7 of which is identical to Figure 1 of the present application, optical signals are averaged by adding in phase successive corresponding portions of the signal over a period of time comprising necessarily a maximum and a minimum value. For the optical signals to be added in phase, they are synchronized to the occurrence of the steepest (R-wave) portions of an electrocardiogram (ECG) waveform, since electrical heart activity occurs simultaneously with the heartbeat. Therefore, the optical signals can be monitored externally, using an ECG signal. Because artifacts are aperiodic, not synchronized signals, they cancel each other out over cumulated time periods, whereby improving the signal to noise ratio and, consequently, increasing the accuracy

of signal processing. Document D1 thus discloses the precharacterising features (a) and (b) of claim 1.

- 3.2 According to the invention the process of using, for example, the R-wave component of an ECG signal as a trigger to synchronize the accumulation of the pulsatile components of the optical signals, is generally called "**C-lock process**". A problem lies in the fact that an ECG signal is not always available and, even when it is, the oximetry system may reject some ECG triggers due to artifacts present in the ECG signal, which thus fail to issue a trigger for the C-lock process.

The problem upon which the application is based is, therefore, to avoid the dependence of an ECG signal to achieve correlation of the optical signal.

The general solution offered by the invention is to replace the ECG signal by a heart rate signal from an external heart rate source in order to implement the C-lock process. In this meaning a "**virtual trigger**" is generated and used as trigger to overlay optical pulse data in a cumulative way.

It is clear from the application as a whole, however, that the expression "**C-lock process**" is generally and primarily used to mean the correlating and averaging aspects of the process. In other words, any trigger can be used when available, either a ECG R-wave such as in document D1 or a "**virtual trigger**" as in the present application, which serves to synchronize and to average optical signal components.

- 3.3 More specifically, the invention resides in the fact

that as long as the frequency of the trigger corresponds to the heart rate, the trigger can be "**arbitrarily**" placed anywhere within the heart rate period. That is, the timing of the trigger can be selected arbitrarily and then its frequency adjusted in accordance with the frequency measured by a heart rate monitor. Since only the frequency of the trigger is important and not its placement within the period, the trigger used in the invention is said "**virtual**", as opposed to a (true) R-wave trigger as known from D1 (cf. Figure 3), the position of which is predetermined by the ECG signal from which it originates.

As a consequence, in the invention the phase relationship between the virtual trigger and the heart rate signal is also "**arbitrary**", contrary to the oximetry system disclosed in document D1, in which, as soon as the occurrence of an R-wave portion is detected, the system determines the time delay by which an optical pulse follows the R-wave and provides a time window during which the optical pulse is likely to occur. Only optical signals detected within said time window are evaluated for acceptance and calculation by a microprocessor. Therefore, in D1 the phase correlation between the trigger and the heart rate signal is not arbitrary but predetermined by both the time delay and the time window.

This arbitrary aspect has been correctly appreciated by the appellant in its letter of 24 March 1998 with attached notes on D1 and accompanying sketches (traces 1 to 4). When, according to the invention, an ECG signal (trace 1) is **not** available, any heart rate monitor (trace 3) can be used to produce a virtual trigger (trace 4), the timing of its occurrence being

arbitrary but having necessarily the same frequency as that of the optical signal (trace 2). In contrast thereto, in document D1, an ECG signal (trace 1) is required, the timing for sampling the optical signal being based on the occurrence of the R-wave component. Therefore, the signal on which processing of the optical signal is based is not arbitrary, but specifically requires identification of the R-wave component and its phase correlation with the start of the processing.

It results therefrom that the claimed expressions "C-lock process", "virtual trigger" and "arbitrary" are sufficiently clearly defined and supported by the application, in accordance with Article 84 EPC. It also results that at least the characterising features (c) to (e) are novel with respect to the disclosure of document D1 (Article 54 EPC).

- 3.4 To produce a virtual trigger according to the invention, any heart rate monitor can be used, as submitted by the appellant and , therefore, also an ECG waveform. The invention, however, starts from the assumption that an ECG signal is **not** available. Such heart rate source is thus excluded.

Document D1 suggests as an alternative (cf. column 4, lines 23 to 33) to use other heart activity parameters than ECG signals to provide an identifiable and detectable signal in response to each heartbeat. However, D1 is silent on how said alternative embodiment is realised. In the Board's view, whatever the heart rate source used in document D1 may be, it is likely that said heart activity parameter will be processed in the same way as disclosed in this

document, that is by selecting and processing a significant portion of the heart rate signal, similarly to the R-wave component of an ECG signal. Therefore, an "**arbitrary virtual trigger**" in the meaning of the present application is not suggested by said alternative embodiment, either.

An important feature of the invention is that, as a consequence of its arbitrariness, the timing of the virtual trigger can be automatically adjusted if the heart rate changes. Thereafter, the virtual trigger functions at the same frequency as the new heart rate. This implies that the heart rate is a function of several heart beats. Therefore, using a heart rate to generate a virtual trigger allows for several accurately timed triggers to be issued in the event the heart rate is not accurately updated every beat (characterising feature (f)). Therefore, this feature is also not disclosed nor suggested by document D1.

It results therefrom, that the subject-matter of independent claims 1 and 6 involves an inventive step with respect to the disclosure of document D1, within the meaning of Article 56 EPC.

4. *The invention in relation to the combination of documents D1 and D2*

4.1 Document D2, like the present invention, relates to an oximetry system for performing measurements of oxygen saturation in blood. The technical problem is also to improve the poor quality of the signal to noise ratio caused by the small amplitude of the received signal or by artifacts due to patient movements and, therefore, to improve the reliability of the oxygen saturation

calculation.

In document D2, measured optical signals are converted into specific electrical signals and then auto-correlation is performed on at least one specific electrical signal, in order to amplify the peaks caused by the arterial blood pulse. Thus, it is possible to trigger on the peaks so as to detect the frequency signal from the auto-correlation function, ie the frequency of the heart rate. In this way it is possible to detect the heart rate without ECG electrodes.

Further, a predefined signal (also called standard function) is produced, which represents an ideal signal for the specific electrical signal and has the same frequency. This standard function is, therefore, comparable to the virtual trigger according to the present invention. Then, cross-correlation is performed between said specific electrical signal and said standard function for achieving amplification of the useful components in the signal and suppression of noise and artifacts. The condition is that the frequencies must be the same. Oxygen saturation is then calculated as long as measuring continues, using the maximum amplitudes of the cross-correlation function (cf. Figure 11)

When comparing document D2 with the invention, the essential distinguishing feature resides in the heart rate source used to produce either the standard function or the virtual trigger, respectively. In both cases, the use of an ECG signal is to be avoided. But in document D2, moreover, no other source than the optical signal itself is to be used. The skilled person is, therefore, led away from using any additional heart

rate monitor.

4.2 Also the combination of the disclosures of documents D1 and D2 would not allow the skilled person to arrive at the claimed subject-matter, since, as mentioned above, the oximetry system of document D1 makes use of an ECG signal, exclusively, so as to provide a not-arbitrary R-wave trigger, whereas document D2 makes use of the optical signal itself, so as to derive a triggering standard function. Further, document D1 may not be combined with document D2, because the respective embodiments use different correlation techniques, both referred to and summarised in document D1 at column 3, lines 54 to 58.

4.3 It results therefrom that the subject-matter of independent claims 1 and 6 is also not suggested by the combination of the teachings of documents D1 and D2. The requirements of Article 56 EPC are thus satisfied.

5. *Appeal fee*

The Board cannot find any procedural violation, much less a substantial violation as is a prerequisite for reimbursement of appeal fees under Rule 67 EPC. The grounds and arguments of the first instance do not constitute a procedural violation for the only reason that they are disputed by the appellant. Nor does a divergence of the technical analysis constitute such violation. The contested decision is based principally on formal issues under Article 84 EPC, which could not be solved during oral proceedings before the first instance. Therefore, it is irrelevant whether further grounds for the refusal such as novelty and inventive step were raised for the first time at the oral

proceedings.

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 on the basis of claims 1 to 7 and the description pages 1 to 22 submitted on 10 January 2002 and the drawings sheets 1 to 10 as published.
3. The request for reimbursement of the appeal fee is rejected.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß