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D E C I S I O N
of 23 June 2003

Case Number: T 1100/00 - 3.2.2.

Application Number: 93300880.7

Publication Number: 0560490

IPC: A61M 16/00

Language of the proceedings: EN

Title of invention:

System and method for controlling a periodically actuated ventilation flow system

Applicant:

PURITAN-BENNETT CORPORATION

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 83

Keyword:

"Sufficiency of disclosure (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 1100/00 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 23 June 2003

Appellant:

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Decision under appeal:

**Decision of the Examining Division of the
European Patent Office posted 19 June 2000
refusing European patent application
No. 93 300 880.7 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noel
U. J. Tronser

Summary of Facts and Submissions

- I. European patent application No. 93 300 880.7 was refused by the Examining Division on the basis of Article 83 EPC on the grounds that the application as amended gave rise to contradictory interpretations. The person skilled in the art, therefore, was not able to determine which one of the interpretations had to be considered for a proper understanding and carrying out of the invention.
- II. The appellant (applicant) lodged an appeal against this decision on 17 August 2000. A statement of grounds was filed on 25 October 2000, along with a report by an expert, a sketch (Figures A and B) and an enlarged Figure 3 of the application as filed.
- III. In a communication dated 14 February 2003 the appellant was informed of the preliminary view of the Board and was proposed a formally acceptable set of claims for the continuation of the examining proceedings.
- IV. In a reply dated 28 April 2003 the appellant gave its general agreement to the Board's proposals and submitted an amended set of claims 1 to 4 along with a new introductory part of description adapted correspondingly.
- V. The appellant requested remittal of the case to the first instance for further prosecution on the substantive issues. As a further request, reimbursement of the appeal fee by reasons of a substantial procedural violation within the meaning of Rule 67 EPC.

VI. The present decision is based on the following application documents:

claims: 1 to 4 submitted on 28 April 2003;

description: pages 1, 2, 3, 4, 4a, 4b, 10 submitted on 28 April 2003, pages 5 to 9 as originally filed, page 11 filed on 3 June 1996;

Figures: 1 to 6 as originally filed.

VII. Independent claim 1 (system) and 3 (method) read as follows:

"A system for controlling the rate of flow of a respiratory gas supplied by a ventilation system (10) for supporting breaths of a patient intubated on the ventilation system (10), the ventilation system (10) including a source (12,14) of respiratory gas, a flow path (26) for said respiratory gas in fluid communication with said patient, a flow control valve (152) for controlling the rate of flow in said flow path (26), and a flow sensor (32) in said flow path (26) for measuring the actual rate of flow in said flow path (26), the control system comprising control means (134) for generating a control signal for operating said flow control valve (152) at least once in a predetermined control interval (n) in a breath (k) to deliver a desired rate of flow in said flow path (26) for each said control interval (n, n+1, ...) in said breath, the control means (134) being connected to said flow sensor (32) and including

a) means for generating an input flow control signal (36) based upon said desired rate of flow for

each control interval (n, n+1 ...) in a current breath (k) ,

b) means (32) for generating a flow rate signal (43) representing the actual rate of flow in the flow path (26),

c) means (140) for comparing said flow rate signal with said input flow control signal (36), and generating a current error signal (error (n)(k)) representing the difference between the actual rate of flow and the desired rate of flow for each said control interval (n, n+1 ...) in said breath (k),

d) means (142,144) for summing each said current error signal for each said control interval in said breath with a sum of all previous error signals that occurred in the corresponding control intervals (n, n+1, ...) of the previous breaths (k-1, k-2 ...) to generate a present correction signal (sum (n+1) (k-1)) which is the sum of all previous error signals that occurred in the corresponding next interval (n+1) of the previous breaths (k-1, k-2 ...) and a future correction component signal (sum (n)(k) for the corresponding control interval (n) in a next breath (k+1),

e) means (144) for storing said present and future correction component signals as the sum of all previous error signals for each appropriate control interval (n, n+1, ...) of the previous breaths (k-1, k-2 ...),

f) means (146,148) for integrating said current error signal and said present correction component signal to generate an integrated present correction component signal (Int. Cmd (n) (k)), and

g) means (150) for summing said input flow control signal (36) and said integrated present correction component signal (Int. Cmd (n) (k)) to generate a command flow signal (Cmd (n) (k)) for said flow control

valve."

"A method of controlling the rate of flow of a respiratory gas supplied by a ventilation system (10) for supporting breaths of a patient intubated on the ventilation system (10) , the ventilation system (10) including a source (12,14) of respiratory gas, a flow path (26) for said respiratory gas in fluid communication with said patient, a flow control valve (152) for controlling the rate of flow in said flow path (26), control means (134) for generating a control signal for operating said flow control valve (152) at least once in a predetermined control interval (n) in a breath (k) to deliver a desired a rate of flow in said flow path (26) for each said control interval (n, n+1 ...) in said breath, and means (32) connected to said control means (134) for measuring the rate of flow in said flow path (26) and generating a flow rate signal (43) representing the actual rate of flow in said flow path (26), the method comprising the steps of:

a) generating an input flow control signal (36) based upon said desired rate of flow for each control interval (n, n+1 ...) in a current breath (k);

b) measuring the actual rate of flow in the flow path (26) and generating a flow rate signal (43) representing the actual rate of flow in the flow path (26);

c) comparing the rate of flow in said flow path (26) with the desired rate of flow in said flow path (26), and generating a current error signal (Error (n)(k)) representing the difference between the actual rate of flow and the desired rate of flow for each said control interval (n, n+1 ...) in said breath (k);

d) summing each said current error signal for each

said control interval in said breath with a sum of all previous error signals that occurred in the corresponding control intervals (n, n+1 ...) of the previous breaths (k-1, k-2 ...) to generate a present correction signal (sum (n+1)(k-1) which is the sum of all previous error signals that occurred in the corresponding next interval (n+1) of the previous breaths (k-1, k-2 ...) and a future correction component signal (sum (n)(k)) for the corresponding control interval (n) in a next breath (k+1);

e) storing said present and future correction component signals as the sum of all previous error signals for each appropriate control interval (n, n+1...) of the previous breaths (k-1, k-2 ...);

f) integrating said current error signal and said present correction component signal to generate an integrated present correction component signal (Int.Cmd(n)(k)); and

g) summing said input flow control signal (36) and said integrated present correction component signal (Int.Cmd(n)(k)) to generate a command flow signal (Cmd(n)(k)) for said control valve (152)."

Reasons for the Decision

1. The appeal is admissible
2. *Amendments*

The amendments to the current version of the claims were made with the view to improve both their clarity and their comprehensibility. Hence, reference signs were introduced after all characterising features and the terminology of the application as filed was

restored in the claims wherever this appeared to be necessary in order to satisfy Article 84 and 123(2) EPC.

In particular, the various error signals and correction component signals were identified in the same way as in Figure 3, which illustrates the principle of the invention, and the terms "present" and "future", which specify the successive correction component signals (feature (d)) as a function of time, were maintained. Further, feature (d) as a whole was re-arranged and completed to incorporate not only the "future" correction component signal $\text{Sum}(n)(k)$ for use as a cumulative error signal for the corresponding control interval (n) of the next breath (k+1), but also the "present" correction component signal $\text{Sum}(n+1)(k-1)$ for use as a cumulative error in the next control interval (n+1) of the current breath (k), both correction signals being stored in memory 144 (cf application, page 9, lines 30 to 31 and from page 9, line 37 to page 10, line 1). Since the provision of both correction component signals represents an essential feature of the solution in order to improve the accuracy of the control system and thereby to reduce the energy required by the patient (cf. from page 7, line 36 to page 8, line 12 and page 8, lines 28 to 32), the incorporation of these signals into feature (d) (claims 1 and 3) was necessary to meet the provisions of Article 84 and Rule 29(1) and (3) EPC.

Method claims 3 and 4 were revised correspondingly to provide consistency with the features of the control system according to claims 1 and 2, respectively.

The introductory part of the description (pages 1 to 4,

4a, 4b) was adapted correspondingly. For the further prosecution of the case, however, the Board finds it appropriate to re-incorporate into the present page 2 of the description (after the first paragraph under the headline "Summary of the invention") the former passage on page 2, lines 31 to 37 of the application as filed which disclosed concisely and properly the principle upon which the invention is based.

3. *Sufficiency of disclosure (Article 83 EPC)*

The present invention as disclosed with reference to Figure 3 provides for an adaptive response to compensate for sustained errors as well as for real time disturbances that occur periodically in the ventilation flow system. The system aims at improving the accuracy of the flow control by approaching the desired flow rate more rapidly than would do a conventional control system. As a result, the energy requirement of a patient for breathing is reduced.

The invention is based on the combination of two concepts:

- a flow rate sensor 32 generates a flow rate measurement signal 43 (see Figure 2), which is sampled (see Figure 5). This signal is then fed back to a comparator summing element 140 for comparison with the desired flow rate signal 36. Thus, each breath (k) is divided into a plurality of control intervals (n) and a correction component is applied to each interval, individually (page 8, lines 3 to 8).
- the control system provides for an adaptive

response based upon past system performances, i.e. with a correction including an integration of flow rate errors during all of the previous breath control intervals (page 2, lines 12 to 17 and page 8, lines 8 to 12).

As it results from the description of Figure 3 the electronic components 142 and 144 form a loop for continuously producing and storing correction component signals (page 8, lines 23 to 32). These signals are formed by integration in a summing element 142 of the error signals already present and stored in a memory 144, keeping in mind that a great number of error signals are produced, that is for each control interval (n, n+1, ..) in a breath (k).

Correction signals are present at both outputs of memory 144. In Figure 3, one output $\text{Sum}(n)(k-1)$ operates as a closed loop to integrate the current error signal $\text{Error}(n)(k)$ arriving at summing element 142 so as to form a "future" correction component signal $\text{Sum}(n)(k)$ which, in turn, is stored in memory 144 (page 9, lines 28 to 34). The other output $\text{Sum}(n+1)(k-1)$ is composed from another accumulation of error signals by using data already available in memory 144 (page 9, lines 37 to page 10, line 1). Both correction signals $\text{Sum}(n)(k-1)$ and $\text{Sum}(n+1)(k-1)$ relate to a past system performance since they accumulate all previous error signals up to the breath (k-1). This represents the very principle of the adaptive response according to the invention.

However, $\text{Sum } (n+1)(k-1)$ is used in first place as "present" correction component signal in order to control the current breath. To this end, this correction signal is added at 146 to the current error signal $\text{Error } (n)(k)$ originating from the summing comparator 140 (page 9, line 35 to page 10, line 1). As explained by the appellant, index $(n+1)$ indicates that it is not the current control interval (n) which is used to form the correction signal, but preferably the next control interval $(n+1)$, in order to compensate for the time delay between the command applied to the flow valve 152 and the effect produced. Since all control intervals are contained in each error signal belonging to a same breath, the skilled person will not have any difficulty to form a correction component signal such as $\text{Sum } (n+1)K-1$ from all data available in memory 144.

The second correction signal $\text{Sum } (n)(k-1)$ is not used directly in the control system. As explained above, it is used to form a next or "future" correction component signal $\text{Sum } (n)(k)$. In the same way as the "present" correction signal $\text{Sum } (n+1)(k-1)$ is used for the current breath (k) , the "future" correction signal $\text{Sum } (n)(k)$ will be used for the next breath $(k+1)$ (cf. page 9, lines 28 to 32).

It results therefrom that although the description of the contested application is succinctly drafted, the invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art following the specific information given on pages 8 to 10 and illustrated in Figure 3. Further, the disclosure is consistent all over the specification and does not suffer from any contradiction or diverging interpretation. In

particular and contrary to the opinion of the first instance, neither the description nor Figure 3 convey the idea that the correction signal $\text{Sum}(n)(k-1)$ should be applied directly to the summing comparator 146 for undertaking a control action on the flow valve. Therefore, the requirements of Article 83 EPC are met.

4. *Remittal*

Since the refusal by the Examining Division was exclusively based on objections under Article 83 EPC, now removed, the Board considers it appropriate to remit the case to the first instance for further prosecution on the substantive issues as requested by the appellant.

5. *Reimbursement*

The appellant requested reimbursement of the appeal fee for the reason of a substantial procedural violation (Rule 67 EPC). It was argued that, contrary to Article 113(2) EPC, the decision of the Examining Division was not based on the text submitted to it, or agreed by the applicant, having regards in particular to page 9 and Figure 3 of the application, which should have been considered in the version as originally filed.

The documents upon which the contested decision is based (cf. point 4 of "Facts and Submissions") refer to page 9 dated 3 June 1996 and Figure 3 submitted during the oral proceedings of 24 May 2000. While Figure 3, supposedly submitted at the oral proceedings could not be found in the file presented for consideration of the Board, page 9 in the version of 3 June 1996 is

manifestly wrong in mentioning "Sum [n][k-1]" at line 37, in conformity with the erroneous Figure 3 submitted on the same date. The correct documents to be considered by the first instance were obviously those filed on 30 July 1999. However, it also results from the reasons of the contested decision (cf. point 4, item ii) on both pages 3 and 4) that the Examining Division actually considered the right documents since as well Figure 3 as page 9, line 37 do correctly mention "Sum (n+1)(k-1)" as the correction signal applied to the summing element 146. Therefore, notwithstanding a mistaken presentation of documents in the decision under appeal, the first instance considered in fact the right documents, i.e. page 9 and Figure 3 as originally filed and re-submitted by letter dated 30 July 1999.

The Board can not therefore, recognise any procedural violation which could justify the reimbursement of the appeal fee.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division for further prosecution on the basis of the documents listed in above point VI with a correction in the description as mentioned in above point 2 of the reasons.
3. The request for reimbursement of the appeal fee is rejected.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß