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**Datasheet for the decision  
of 23 August 2011**

**Case Number:** T 0845/08 - 3.2.02

**Application Number:** 01983611.3

**Publication Number:** 1452134

**IPC:** A61B 5/087

**Language of the proceedings:** EN

**Title of invention:**

Multi-spirometer and method for measuring ventilatory function  
by spirometry

**Applicant:**

Health Solutions, S.L.

**Headword:**

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**Relevant legal provisions:**

EPC Art. 83, 84

**Relevant legal provisions (EPC 1973):**

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**Keyword:**

"Clarity (no)"

"Sufficiency of the disclosure (no)"

**Decisions cited:**

T 0287/08

**Catchword:**

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Case Number: T 0845/08 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 23 August 2011

**Appellant:** Health Solutions, S.L.  
Calle Balmes 233- 2-2  
E-08006 Barcelona (ES)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 23 November 2007  
refusing European patent application  
No. 01983611.3 pursuant to Article 97(1) EPC  
1973.

**Composition of the Board:**

**Chairman:** D. Valle  
**Members:** C. Körber  
J. Geschwind

## Summary of Facts and Submissions

- I. The appellant (applicant) lodged an appeal on 20 December 2007 against the decision of the Examining Division posted on 23 November 2007 to refuse the application. The fee for the appeal was paid the same day and the statement setting out the grounds for appeal was received on 3 April 2008.
- II. The application was refused on the basis of Articles 83, 84 and 123 (2) EPC.
- III. On request of the appellant, oral proceedings have been held the 23 August 2011. The appellant, although duly summoned, was not represented at the oral proceedings. In accordance with the provision of Rule 115 (2) EPC, the proceedings were continued without him.
- IV. In the written submissions the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of a main or one of the auxiliary requests 1 to 5 all filed with letter of 3 April 2008.

The requests were specified as follows:

main and first to fourth auxiliary requests:

- claims 1 to 12
  - description: pages 1 to 23 and 4A, 4B
- all filed with letter of 3 April 2008;

fifth auxiliary request:

- claims 1 to 8
  - description: pages 1 to 23 and 4A, 4B
- all filed with letter of 3 April 2008.

V. Claim 1 of the main request reads as follows:

"Method to measure the ventilatory function by spirometry, capable of obtaining respiratory restriction and obstruction values of a patient, by using an electronic spirometer provided with flow detector means, microprocessor control means to carry out calculations on the basis of measured data, and means associated with said microprocessor to store the measured results, to visualize the results and to compare the stored results, characterized by

- capturing data by means of said spirometer in response to a VC maneuver, during which a patient, starting from a maximal inspiration, slowly exhales air until no more air can be expelled,
- capturing data by means of said spirometer in response to an FEV maneuver consisting of a forced and continuous exhalation from maximal inspiration, and exhaling the air until a minimum predetermined time has elapsed and by processing by computer means the expiration flow data obtained during the FEV-maneuver and calculating an FEV maneuver index consisting of a 2-digit numerical expression based on a flow/time curve, which reflects the FEV maneuver performed by the patient, consisting in taking as the first digit for the index the time measurement in tenths of a second, from the maximum flow point until the first second of the flow/time curve and as the second digit for the

index the time in tenths of a second of descending and concave curve viewed from above, from the maximum flow point until the first second, thereby classifying the results according to a weighted score from 99 to 00."

Claim 1 of the first auxiliary request is derivable from claim 1 of the main request by deleting the feature at the end of the claim:

", thereby classifying the results according to a weighted score from 99 to 00".

Claim 1 of the second auxiliary request is derivable from claim 1 of the main request by adding the clause:

" ... consisting in taking as the first digit for the index the time measurement in tenths of a second, from the maximum flow point until the first second of the flow/time curve and as the second digit for the index the time in tenths of a second of descending and concave part of the flow/time curve viewed from above, from the maximum flow point until the first second, thereby classifying the results according to a weighted score from 99 to 00."

Claim 1 of the third auxiliary request is derivable from claim 1 of the main request by adding the clauses:

" ... consisting in taking as the first digit for the index the time measurement in tenths of a second, from the maximum flow point until the first second of the flow/time curve, informing of the initial exhalation intensity, and as the second digit for the index the time in tenths of a second of descending and concave

curve viewed from above, from the maximum flow point until the first second, informing of the intensity and uniformity of the expiration of air during the first second; hereby classifying the results according to a weighted score from 99 to 00."

Claim 1 of the fourth and fifth auxiliary requests is a combination of claims 1 of the second and third auxiliary requests.

- VI. The appellant argued in particular that the it was clear from the application how to determine the second digit of the index. In support of his argument he filed as annexes A and B two diagrams in order to exemplarily illustrate by means of a concrete case the method for determining the second digit.

### **Reasons for the Decision**

1. The appeal is admissible.
2. Clarity (Article 84 EPC) and sufficiency of the disclosure (Article 83 EPC) of all the requests on file.

As already stated in the decision under appeal, the sentence in claim 1 of all the requests:

"as the second digit for the index the time in tenths of a second of descending and concave curve viewed from above, from the maximum flow point until the first second"

is not clear. Furthermore the application does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art because it is not clear from the whole application how exactly the second digit for the index has to be determined. The description merely contains the same wording of the claim as cited above and the additional statement "informing us whether the air exhaled during the first second was strong, continuous and uniform, and that the exhalation during the first second was maintained", but does not provide any further information in this regard. The drawings do not comprise a single example either illustrating a flow/time curve, let alone the determination of the second digit of the index.

In particular, it remains entirely obscure how the index has to be determined in the case of various "descending and concave", non contiguous sections of the curve, as it can occur when the flow/time curve is not monotonously decreasing after the maximum flow point.

The expressions: "descending" and "concave from above" may have a precise meaning for a well-defined geometrical curve. "Descending" means in such case that the first derivative of the curve is negative, and "concave from above" could mean that the second derivative is positive. However, the flow/time curve of the alleged invention is not a well-defined geometrical curve, but it results from an experimental test. Experimental curves can present irregularities which have to be specifically taken into consideration and can not as a rule be dealt with on the basis of a

simple mathematical formula. In the present case there is no reference throughout the application to the mathematical, precise meaning of the two contested expressions. On the contrary, the meaning of the expressions in the application remains vague.

Even if one would take advantage of the precise, mathematical meaning of those expressions in order to try to determine the second digit, the results would be inconsistent with what the appellant himself stated referring to the example submitted with the statement of grounds of appeal as annexes A and B. The appellant argued that the second digit in annex A was 8, whereas the first digit was 9 (see page 4 of the statement of grounds, line 11 with line 34). However, it appears that starting from the maximum flow point (corresponding to the first digit 9) the curve is almost immediately descending and concave, so that the second digit should be approximately 9 and not 8 as the appellant maintained. Furthermore, referring to annex B a rough calculation of the second index on the basis of the mathematical definition would lead to a value substantially less than 5, which is the value that the appellant gives for the second digit. It is to be noted, however, that the curves shown in both annexes do not form part of the disclosure.

Accordingly, the expression "as the second digit ..." in claim 1 is unclear, and the description, which itself is unclear, is not suitable for giving a meaning to the claim (cf. T 287/08).

Since this lack of determination affects an essential feature of the claim 1 of all the requests, claim 1 of



all the requests is not clear (Article 84 EPC) and the application does not comply with Article 83 EPC.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

D. Sauter

D. Valle