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DECISION of 30 April 1996

Case Number: T 0218/94 - 3.2.2

Application Number: 90850183.6

Publication Number: 0399974

IPC: A61B 5/022

Language of the proceedings: EN

Title of invention:

A method for measuring blood pressure and a blood-pressure measuring device for carrying out the method

Applicant:

SJÖNELL, Göran

Opponent:

Headword:

Relevant legal provisions:

EPC Art. 56, 83

Keyword:

"Disclosure - sufficiency - skilled person"

"Inventive step (yes)"

Decisions cited:

T 0010/86

Catchword:



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Boards of Appeal

Chambres de recours

Case Number: T 0218/94 - 3.2.2

DECISION
of the Technical Board of Appeal 3.2.2
of 30 April 1996

Appellant:

SJÖNELL, Göran Askrikevägen 11

S-181 46 Lidingö (SE)

Representative:

Onn, Thorsten

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Decision under appeal:

Decision of the Examining Division of the European Patent Office dated 10 November 1993 refusing European patent application No. 90 850 183.6

pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman:

H. Seidenschwarz

Members:

P. Dropmann

J.-C. De Preter

Summary of Facts and Submissions

I. A Notice of Appeal was filed against the decision of the Examining Division refusing European patent application No. 90 850 183.6.

The Examining Division held that the application did not meet the requirement of Article 83 EPC in that it did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In addition, the Examining Division raised an objection under Article 56 EPC.

- II. Following a telephone conversation between the appellant's representative and the rapporteur raising an objection under Article 84 EPC, the appellant submitted an amended set of claims 1 and 2.
- III. The appellant requested that the decision under appeal be set aside and a patent granted on the basis of the following documents:
 - claims 1 and 2 as filed with the letter of 30 April 1996,
 - description pages 1 to 6 as originally filed (however, the word "dependent" at the end of line 22 at page 4 is to be deleted),
 - single figure as originally filed.
- IV. Claims 1 and 2 read as follows after insertion of the word "converts" after the word "which" in claim 2, line 21:

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- "1. A method for measuring blood pressure with the aid of a blood pressure cuff (1) intended to be placed around the upper arm or the thigh and connected to a pressure sensor (2), characterized in that a pressure level value from the pressure sensor (2) and a pulse frequency value are sent to a correction unit (4) which automatically corrects the pressure value received from the blood pressure cuff (1) with respect to pulse frequency and pressure level, said pulse frequency being determined with the aid of a known oscillometric technique, and in that the correction unit (4), upon insertion of such parameters as age, sex and upper-arm (thigh) circumference, is also operative to make corrections for the blood-pressure measuring errors that are contingent on variations in age, sex and upper-arm (thigh) circumference, whereby a corrected and essentially correct readable blood-pressure value is obtained."
- A blood pressure measuring device comprising a cuff (1) intended to be placed around the upper arm or the thigh, a pressure sensor (2) connected to the cuff and a display unit (8) which is connected to the cuff and which is operative to display the systolic pressure and the diastolic pressure, characterized in that the measuring device also includes a correction unit (4) into which a pressure level value from the pressure sensor (2) and a pulse frequency value are introduced and used as the basis for automatically correcting the pressure value obtained from the cuff (1) with respect to pulse frequency and pressure level; and in that the measuring device also includes an infeed unit (6) which is connected to the correction unit and which converts inserted information concerning age, sex and upper arm (thigh) circumference to signal form, said correction unit (4) functioning to correct the pressure value obtained from the cuff (1) in dependence on the signals

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sent from the infeed unit (6) with respect to age, sex and upper-arm (thigh) circumference, to a corrected, true blood-pressure value which can be read-off."

Reasons for the Decision

- 1. The appeal is admissible.
- No objections arise against claims 1 and 2 under Articles 123(2) and 84 EPC and Rule 29 EPC.
- 3. Sufficiency of disclosure
- 3.1 According to Article 83 EPC, the disclosure of the invention must be sufficiently clear and complete to enable the skilled reader to carry out the invention. Thus, the disclosure is not addressed to the public at large, but rather to the person skilled in the art who is presumed to be an ordinary practitioner, aware of what was common general knowledge in the art at the relevant date. In point 4 of Decision T 10/86 of 1 September 1988 (unpublished) it was held that Article 83 is to be interpreted as meaning that the alleged invention must be capable of being performed by the skilled reader on the basis of what was originally disclosed in the application, without his needing to add any further inventive effort.
- As to the present case, the Examining Division held that the invention was not disclosed in sufficient detail to enable the skilled person to perform it and that, in particular, the application lacked any example of a "correction unit" capable of actually producing a correct blood pressure value on the basis of the pressure value obtained from the cuff and the further

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parameters such as pulse frequency, pressure level, age, sex, and upper arm or thigh circumference as set out in independent claims 1 and 2. The application did not even specify according to which function or algorithm the various correction parameters set out in the claims should be processed in order to provide effective pressure correction. The information given in the application could, in the view of the Examining Division, hardly enable the skilled person to devise and implement a correctly operating device using only his general knowledge and without the need for overcoming undue technical difficulties. The skilled person would rather have to perform lengthy experimentation and statistical data processing and to design adapted electronic circuits or programs, all of which would call for technical skills well above the skilled person's normal ability.

3.3 The Board cannot accept these arguments. In its view the invention can be performed by the skilled person, without the exercise of an inventive effort, on the basis of the information disclosed in the application, taken together with common general knowledge.

As pointed out by the appellant, the influence on the measured blood pressure value of the parameters mentioned in the application, i.e. pulse frequency, pressure level, age, sex, and arm or thigh circumference, and thus the systematic errors can be determined through ordinary, non-inventive test, for example by comparison of auscultatory indirect (non-invasive) blood pressure readings, such as those obtained with cuffs, with direct intraarterial (invasive) pressure readings. The correlation factors of these parameters, derived from such experimentation and statistical data processing, are combined in the correction unit specified in claims 1 and 2 which

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automatically corrects the pressure value which is received from the blood pressure measuring cuff and is dependent on variations of the parameters mentioned.

In the Board's judgement, the skilled person, on the basis of his common general knowledge, would know according to which function or algorithm the correlation factors should be processed in order to achieve effective pressure correction. Such function or algorithm need not, therefore, be explicitly mentioned in the application, irrespective of whether there is a single or multiple dependency of the various parameters. The reference in the claims to the correction unit (4) for automatically correcting, with respect to the said parameters, the pressure value received from the cuff is sufficient for the skilled person to produce this correction unit, without the need for any further details as to the design of adapted electronic circuits or programs. Such details lie well within the realm of the normal ability of the skilled person. The claimed method and device can be put into practice by the skilled person without any inventive effort or undue burden. The correction unit according to the invention is a common, programmable computer receiving the signals measured by the cuff and correcting these signals to true values using, for example, stored regression coefficients as stated in the description.

- 3.4 For this reason, the Board is satisfied that the patent application discloses the invention as defined in the claims in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, as is required under Article 83 EPC.
- 3.5 Concerning the objection under Rule 27(1)(e) EPC raised by the Examining Division in the appealed decision, reference is made to page 4 of the description which

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describes the claimed method and device and explicitly discloses that the automatic correction, by the correction unit, of the pressure value sensed by the cuff can be effected with the aid of regression coefficients. The description thus describes in detail at least one way of carrying out the invention, in compliance with the requirement of Rule 27(1)(e) EPC. Examples are only necessary in appropriate cases.

4. Novelty

None of the documents mentioned in the search report and in the statement of grounds (Enclosures 1 to 5) discloses a method or device having all the features specified in claim 1 or 2. In particular, no method or device for measuring blood pressure is known in which a correction unit automatically corrects the pressure value received from a blood pressure cuff with respect to the parameters pulse frequency, pressure level, age, sex, and arm or thigh circumference. The claimed method and device are, therefore, novel over these documents within the meaning of Article 54 EPC.

5. Inventive step

As stated in the application, serious measurement errors can occur when measuring blood pressure with the aid of a universal cuff used for all patients, since systematic errors, due to the influence of the parameters pulse frequency, pressure level, age, sex, and arm or thigh circumference, are added to the true blood pressure value. The problem addressed by the present invention lies in the provision of a method and device which eliminate such errors to the greatest possible extent. The problem is solved in accordance with claims 1 and 2 by providing a correction unit which automatically

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corrects the pressure value obtained from the blood pressure cuff taking account of the parameters mentioned above.

5.2 None of the prior art documents of the proceedings suggests the provision of such a correction unit, which leads to an effective and true-measuring blood pressure measuring device and method and avoids the need for differently sized cuffs. It is true that documents WO-A-88/03387 and WO-A-88/05283, both cited in the search report, mention that, in a blood pressure monitoring apparatus, information concerning the subject, such as the subject's age, sex, weight, height and arm or wrist dimensions, may be entered into the memory of a computer in which diastolic and/or systolic pressure and pulse amplitude values obtained from transducer elements are stored. This information, however, is used to estimate the diameter of the artery underlying the transducer elements.

In the absence of any hint in the prior art that the systematic errors occurring when measuring blood pressure with a universal cuff could be eliminated and thus the accuracy of such indirect blood pressure measurement increased in the way set forth in claims 1 and 2, the presence of an inventive step as defined in Article 56 EPC has to be acknowledged.

6. Hence, the invention according to claims 1 and 2 has to be considered patentable having regard to Articles 52(1), 54, 56 and 83 EPC.

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Order

For these reasons it is decided that:

- The decision under appeal is set aside.
- 2. The case is remitted to the first instance with the order to grant a patent in the following version:
 - claims 1 and 2 as filed with the letter of 30 April 1996 (however, the word "converts" is to be inserted after "which" in claim 2, line 21),
 - description pages 1 to 6 as originally filed (however, the word "dependent" at the end of line 22 at page 4 is to be deleted),
 - single figure as originally filed.

The Registrar:

S. Fabiani

The Chairman:

H Soidonaghwara

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