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Datasheet for the decision of 25 October 2023

Case Number: T 1446/20 - 3.5.03

Application Number: 11712389.3

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Language of the proceedings: EN

Title of invention:
Residual compensation for a biosensor

Applicant:
Ascensia Diabetes Care Holdings AG

Headword:
Analyte-concentration errors/ASCENSIA

Relevant legal provisions:
EPC Art. 84
RPBA 2020 Art. 12(8)

Keyword:
Decision in written proceedings - (yes): indication of appellant's non-attendance - oral proceedings neither necessary nor expedient
Clarity - main and auxiliary requests (no)

Decisions cited:
T 1560/19

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Case Number: T 1446/20 - 3.5.03

D E C I S I O N
of Technical Board of Appeal 3.5.03
of 25 October 2023

Appellant: (Applicant)	Ascensia Diabetes Care Holdings AG Peter-Merian Strasse 90 4052 Basel (CH)
Representative:	Cohausz & Florack Patent- & Rechtsanwälte Partnerschaftsgesellschaft mbB Postfach 10 18 30 40009 Düsseldorf (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 10 January 2020 refusing European patent application No. 11712389.3 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	K. Bengi-Akyürek
Members:	K. Peirs
	F. Bostedt

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division to refuse the present application based on a main request and seven auxiliary requests (first to seventh auxiliary requests). These claim requests were deemed not to be allowable under Articles 83 and 84 EPC.

II. The applicant (appellant) requests that the decision under appeal be set aside and that a patent be granted according to the claims of the **main request** underlying the appealed decision (re-filed with the statement setting out the grounds of appeal) or, in the alternative, of **eight auxiliary requests**.

Seven of these eight auxiliary requests correspond to the auxiliary requests underlying the appealed decision (re-filed with the statement setting out the grounds of appeal). The remaining auxiliary request ("**auxiliary request 5a**") was filed for the first time with the statement setting out the grounds of appeal.

III. The appellant was summoned to oral proceedings before the board. A communication was issued under Article 15(1) RPBA 2020 including the board's negative preliminary opinion regarding clarity (Article 84 EPC) as regards all claim requests on file.

IV. In a written reply, the appellant stated that it would not be attending the arranged oral proceedings.

V. Subsequently, the oral proceedings were cancelled.

VI. Claim 1 of the **main request** reads as follows (board's feature labelling):

(a) "A method for determining an analyte concentration in a sample, comprising:
(b) generating an output signal responsive to a concentration of an analyte in a sample and an input signal, the output signal including errors from multiple error sources that contribute to a total error;
(c) compensating the output signal with a primary function and a first residual function to determine a compensated output signal,
(d) wherein the primary function is in the form of an index function that is determined using error parameter values extracted directly or indirectly from an analyte analysis or from a source independent of an analyte responsive output signal,
(e) the primary function compensating a primary error in the output signal that is at least 50% of the total error and that compensates at least one of a temperature error or a hematocrit error, the temperature error and the hematocrit error having been previously determined in a controlled environment prior to determining the analyte concentration in the sample;
(f) the first residual function compensating a remaining error in the output signal until errors become random, the remaining error being an operating condition error introduced by user self-testing outside of the controlled environment and prior to determining the analyte concentration in the sample;
(g) providing the compensated output signal in which both the primary error and the remaining error have

been compensated, respectively, by the primary function and the first residual function; and

(h) determining the analyte concentration in the sample from the compensated output signal in which the total error has been reduced to exclude the primary error and the remaining error.".

VII. Claim 1 of the **first auxiliary request** differs from claim 1 of the main request in that

- the clauses "that is at least 50% of the total error" in feature (e) and "until errors become random" of feature (f) are deleted

and in that

- feature (c) is replaced by the following feature (board's feature labelling and highlighting, the latter reflecting amendments vis-à-vis feature (c)):

(i) "compensating the output signal with a primary function, previously stored in a storage medium (728), and a first residual function, wherein a finite number of first residual functions is predetermined and previously stored in the storage medium (728), to determine a compensated output signal,".

VIII. Claim 1 of the **second auxiliary request** differs from claim 1 of the first auxiliary request in that it comprises, between features (f) and (g), the following feature (board's feature labelling):

(j) "wherein the one or more residual functions are determined by performing a multi-variable

regression using the observed residual errors as the responder and various terms from internal and external signals as the predictors,".

IX. Claim 1 of the **third auxiliary request** differs from claim 1 of the second auxiliary request in that it comprises, between features (j) and (g), the following feature (board's feature labelling):

(k) "wherein the residual function determination method comprises further: selecting multiple error parameters as potential terms in the first residual function, the error parameters being any value responsive to one or more errors in the output signal; determining a first exclusion value for the potential terms; applying an exclusion test responsive to the first exclusion value for the potential terms; identifying one or more of the potential terms for exclusion from the first residual function; and excluding one or more identified potential terms from the first residual function,".

X. Claim 1 of the **fourth auxiliary request** differs from claim 1 of the first auxiliary request in that

- feature (i) is replaced by the following feature (board's feature labelling and highlighting, the latter reflecting amendments vis-à-vis feature (i)):

(l) "compensating the output signal with a primary function, previously stored in a storage medium (728), and a first residual function, wherein a finite number of first residual functions is predetermined and previously stored in the

storage medium (728), wherein one first residual function is stored for a low volume underfill event and a further first residual function is stored for a high volume underfill event, to determine a compensated output signal,"

and in that

- it comprises, between features (f) and (g), the following feature (board's feature labelling):

(m) "wherein the first residual function to be applied is determined from the stored first residual functions based on a detected low volume underfill event or a detected high volume underfill event,".

XI. Claim 1 of the **fifth auxiliary request** differs from claim 1 of the fourth auxiliary request in that it further comprises, between features (l) and (d), the following feature (board's feature labelling):

(n) "wherein an electrode sensor is provided, wherein on entry to the test sensor (704) the sample crosses a first electrode (A) before a second (B), the second (B) before a third (C), and the third (C) before a fourth (D), wherein the time required for the sample to reach between electrodes (B) and (C) and the time for reaching between electrodes (C) and (D) may be expressed as BC and CD respectively, and wherein the BC time is associated with the low volume underfill event and the CD time is associated with the high volume underfill event,".

XII. Claim 1 of the **auxiliary request 5a** differs from claim 1 of the fifth auxiliary request in that it

further comprises, between features (m) and (g), the following feature (board's feature labelling):

(o) "the first residual function for the detected low volume underfill event being detected during the BC time, the first residual function for the detected high volume underfill event being detected during the CD time,".

XIII. Claim 1 of the **sixth auxiliary request** differs from claim 1 of the second auxiliary request in that it further comprises, between features (j) and (g), the following feature (board's feature labelling):

(p) "after application of the first residual function, a second residual function is applied for reducing remaining residual errors, wherein the second residual function may be selected to compensate errors arising at extreme temperature of 5°C and/or sample hematocrit levels at 70% Hct,".

XIV. Claim 1 of the **seventh auxiliary request** reads as follows (board's feature labelling):

(q) "A method of operating a biosensor system (700) for determining an analyte concentration in a biological fluid sample when at least one operating condition error is introduced into an analysis by user self-testing, the method comprising:

(r) providing a biosensor system (700) in the form of an analytical instrument including a measurement device (702) having electrical circuitry (716) communicatively coupled to a processor (722), a storage medium (728), a signal generator (724), and a sensor interface (718), the processor (722) having instructions and data stored in the storage

medium (728), and a test sensor (704) having a base (706) and a sample interface (714), the base (706) forming a reservoir (708) and a channel (710) with an opening (712), the base (706) further having a surface on which at least one working electrode (732) and at least one counter electrode (734) are disposed, the reservoir (708) being in electrical or optical communication with the measurement device (702), the sample interface (714) having conductors connected to the working electrode (732) and the counter electrode (734);

(s) determining in a controlled environment, prior to the user self-testing, a primary error of an uncompensated analyte concentration, the primary error being at least 50% of a total error of the uncompensated analyte concentration and including at least one of a temperature error or a hematocrit error; and

(t) subsequently and outside the controlled environment, initiating the user self-testing via the biosensor system (700) to determine a compensated analyte concentration, the user self-testing including:
receiving the biological fluid sample in the opening (712), the biological fluid sample flowing through the channel (710) to fill at least in part the reservoir (708) of the test sensor (704),
introducing the operating condition error during the user self-testing but prior to determining the compensated analyte concentration in the biological fluid sample,

(u) in response to receiving the biological fluid sample in the reservoir (708), generating an input signal, by the processor (722), from the signal generator (724), transmitting the input signal by

the sensor interface (718) to the sample interface (714) for applying the input signal to the biological fluid sample,

(v) in response to the input signal and the uncompensated analyte concentration, receiving and measuring, by the processor (722), an output signal from the working electrode (732) and the counter electrode (734) of the test sensor (704),

(w) compensating, by the processor (722), the primary error in the output signal with a primary function, the primary function being in the form of an index function that is determined using error parameter values from an analyte analysis or from a source independent of an analyte-responsive output signal,

(x) compensating, by the processor (722), a remaining error of the total error in the output signal with a first residual function, the first residual function compensating the remaining error until errors become random, the remaining error being the operating condition error,

(y) determining a compensated output signal based on the compensating of the primary error and the remaining error in the output signal, and

(z) determining, by the processor (722), the compensated analyte concentration in the biological fluid sample from the compensated output signal in which the total error has been reduced by compensating for the primary error and the remaining error.".

Reasons for the Decision

1. *Decision in written proceedings*

As the appellant effectively withdrew its request for

oral proceedings by declaring its intent not to attend them, and as the board does not consider the conduct of oral proceedings to be expedient either (cf. Article 116(1) EPC), the decision is handed down in written proceedings (Article 12(8) RPBA 2020).

2. *Technical background*

2.1 The present application concerns biosensor systems in which the concentration of an analyte such as a biological fluid (e.g. blood, saliva or urine) sample is analysed. This analysis can then lead to conclusions on, for instance, the glucose level of a diabetic individual.

2.2 There are many factors that impact the accuracy of the analysis of the analyte concentration. To give an example, it will make a difference whether the sample is taken from a reservoir outside a living organism or from the living organism itself. It also makes a difference whether the sample is taken by specifically trained staff or by the layman user themselves. In the latter case, the sample's concentration can more easily be biased, for instance, by the user's shaky hands or by an inappropriate sample size (e.g. "underfill" or "overfill" conditions).

2.3 The present application aims to improve the accuracy with which sample analyte concentrations are determined. It allegedly does so by means of two error-correcting functions: a *primary function* that compensates half or more of the "total error" (**feature (e)**) and a *first residual function* that compensates residual errors "until the errors become random" (**feature (f)**).

3. *Main request: claim 1 - clarity*

3.1 The board agrees with Reasons 1.1 to 1.4 of the appealed decision that claim 1 is not clear (Article 84, second sentence, EPC).

3.2 The appellant's arguments in this respect did not convince the board because they either amount to mere statements or draw upon the description to construe claim 1. The boards recalls that, when assessing the clarity of the claim within the meaning of Article 84, second sentence, EPC, the claims should essentially be read and interpreted by a skilled reader based on their own merits, i.e. without the need of resorting to the description (cf. **T 1560/19**, Reasons 2.1). The board could not appreciate from the appellant's arguments

- how the skilled reader would actually construe **features (a) to (h)**

and

- why this would be the case.

3.3 In the board's view, the following clarity deficiencies of **features (b) and (d) to (f)**, are the reason for the clarity objections raised

- in Reasons 1.1 and 1.2 of the appealed decision regarding the "desired effect"

and

- in Reasons 1.4 of that decision concerning the expression "residual function":

3.3.1 As regards **feature (b)**, no reference signal is specified with which the "errors" and "total error" could be defined. Typically, errors that are included in the "output signal" will depend

- on the method that is used to determine the "analyte concentration" mentioned in claim 1

and

- on the nature of the "multiple error sources" of feature (b).

Specifying either this method or the error sources' nature might have given the skilled reader at least some guidance as to the determination of the terms "errors" and "total error" according to feature (b). However, neither is mentioned in claim 1. Even the term "input signal" of feature (b) remains unspecified. As a result, claim 1 does not provide the skilled reader with *any* indication on how to construe the "errors" and "total error" of feature (b) for a given output signal.

3.3.2 **Feature (d)** concerns "an analyte analysis". It would not be clear for the skilled reader whether the "analyte" considered in this analysis is related to the analyte mentioned in **features (a), (b), (e), (f) and (h)**. The same applies to the "analyte" of the term "an analyte-responsive output signal" according to feature (d). Moreover, if the "source" mentioned in feature (d) is supposed to be "independent of an analyte-responsive output signal" (emphasis added), it would not be clear for the skilled reader how "error parameter values" extracted from that source according to feature (d) could possibly relate to a "primary function" with which a "primary error" in the output

signal according to **feature (e)** can be compensated.

3.3.3 Further as to **feature (e)**, it would not be clear for the skilled reader how the "primary error", being at least 50% of the total error of the "output signal", can be determined for any arbitrary output signal. This is because the "total error" is not clearly defined for such an arbitrary output signal, as set out in point 3.3.1 above. Moreover, the skilled reader would be in doubt as to whether the "temperature error" or "hematocrit error" constitutes a part of the "errors" or "total error" of feature (b). The "hematocrit error" may not even be relevant at all because not every analyte concentration covered by features (a), (b), (e), (f) and (h) necessarily involves a hematocrit level.

Also, the term "controlled environment" mentioned in feature (e) is not clear, given that claim 1 is silent as to the conditions of the environment which are supposed to be "controlled".

Moreover, it is not apparent whether the expression "prior to determining the analyte concentration in the sample" of feature (e) is supposed to refer to the "determining" step of feature (a) or that of feature (h). In the former case, determining the temperature error and the hematocrit error according to feature (e) takes place *before* the generating step of feature (b), whereas in the latter case it can take place *after* this generating step.

3.3.4 Regarding **feature (f)**, it would not be apparent to the skilled reader how the term "remaining error" relates to the "errors" or "total error" of feature (b). Also, the skilled reader would not be able to recognise

whether a given "remaining error" relates to an "operating condition error" as required by feature (f): such a relation is not necessarily present for all possible remaining errors. The "analyte concentration" according to features (a), (b), (e), (f) and (h) does not even necessarily involve any "user self-testing" as mentioned in feature (f). Even if the skilled reader were able to somehow make sense of the term "remaining error", the expression "until errors become random" would not be clear because, whatever may be meant in this expression by the terms "errors" and "random", not all conceivable first residual functions are necessarily suitable to compensate the "remaining error" of feature (f).

3.4 Hence, claim 1 of the main request does not fulfil the clarity requirement of Article 84, second sentence, EPC.

4. *Auxiliary requests: claim 1 - clarity*

4.1 Regardless of any admittance issues as to auxiliary request 5a, the board holds that claim 1 of all of the **auxiliary requests** on file suffers *at least* from some of the deficiencies mentioned in point 3 above for claim 1 of the main request:

4.1.1 Concerning all of the **auxiliary requests** apart from the **seventh auxiliary request**, the deletion of the clauses referred to in the first dash of point VII above only overcomes one of the objections raised in point 3.3.4 above. The remaining objections mentioned in this point and those raised in points 3.3.1 to 3.3.3 above are not overcome by any of **features (i) to (p)**.

4.1.2 As regards the **seventh auxiliary request**, it goes without saying that a favourable outcome regarding the corresponding U.S. counterpart application does not warrant the allowability of this request under the EPC. For instance, the board has doubts as to whether claim 1 of the seventh auxiliary request complies with Article 123(2) EPC. Irrespective of these doubts, the board notes that the examining division essentially raised in the last paragraph of section "II. Grounds for the decision" of the appealed decision the same objections as regards claim 1 of the seventh auxiliary request as for claim 1 of the main request. The board agrees with this in the sense that at least some of the clarity objections raised in point 3 above apply also to claim 1 of the seventh auxiliary request.

In particular, the following is noted:

- Concerning **feature (s)**, the objections raised in the first and second paragraph of point 3.3.3 above still apply. To explain this in more detail, the "primary error" mentioned in this feature is not clear because the "total error" according to this feature is not clearly defined. Moreover, the skilled reader would be in doubt as to whether the "temperature error" or "hematocrit error" according to feature (s) are part of the "total error" mentioned in this feature or whether they are, for instance, part of the "errors" according to feature (x). Also, the term "controlled environment" according to feature (s) is not clear because claim 1 of auxiliary request 7 is silent as to the conditions of the environment which are supposed to be "controlled". Even with the use of the "biosensor system" according to **features (q) and (r)**, the biological fluid sample of feature (q)

does not necessarily relate to a "hematocrit level". It could, for instance, concern a sample from a non-human biological fluid, such as from a fermentation reactor with biological material. Even if one were to restrict the biological fluid sample of feature (q) to one taken from a human biological fluid, it can still concern a saliva or urine sample (cf. paragraph [002] of the description of the present application) rather than a blood sample.

- As to **feature (u)**, similar objections as those raised in point 3.3.1 above apply because specifying a "signal generator" as in features (r) and (u) does not render more apparent

  - the method that is used to determine the analyte concentration mentioned in claim 1

  and, hence,

  - the underlying "errors" mentioned in feature (x) and the "total error" referred to in feature (s).

  Moreover, the "measurement device" of **feature (r)**, even when combined with the "receiving and measuring" step of **feature (v)**, only narrows down the method that is used to determine the analyte concentration to the extent that two electrodes are involved in this method and that some electrical or optical communication must take place. This still does not allow the skilled reader to determine in a clear manner the "errors" according to feature (x) and the "total error" specified in feature (s).

- As regards **feature (w)** and similarly to point 3.3.2 above, it is not clear whether the term "analyte" in the expressions "an analyte analysis" and "an analyte-responsive output signal" mentioned in this feature is indeed related to the "analyte" mentioned in features (q), (s), (t) and (v).

- With respect to **feature (x)**, the expression "until errors become random" is still not clear for similar reasons as set out in point 3.3.4 above: besides the terms "errors" and "random" not being well-defined, not all conceivable "first residual functions" are necessarily suitable to compensate the "remaining error" as required by this feature.

4.2 In conclusion, the auxiliary requests on file are also not allowable under Article 84 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

B. Brückner K. Bengi-Akyürek

Decision electronically authenticated