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Datasheet for the decision of 14 March 2022

Case Number: T 2681/16 - 3.2.02

Application Number: 07716416.8

Publication Number: 1988821

IPC: A61B5/00

Language of the proceedings: EN

Title of invention:
METHOD, SYSTEM AND COMPUTER PROGRAM PRODUCT FOR EVALUATION OF BLOOD GLUCOSE VARIABILITY IN DIABETES FROM SELF-MONITORING DATA

Applicant:
UNIVERSITY OF VIRGINIA PATENT FOUNDATION

Relevant legal provisions:
EPC Art. 56, 84
RPBA 2020 Art. 13(2)

Keyword:
Amendment after summons - taken into account (yes)
Claims - support in the description (yes / no)
Inventive step - mixture of technical and non-technical features - technical effect credible (yes / no)

Decisions cited:
G 0001/19

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Case Number: T 2681/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 14 March 2022

Appellant: (Applicant)	UNIVERSITY OF VIRGINIA PATENT FOUNDATION 250 West Main Street, Suite 300 Charlottesville, VA 22902 (US)
Representative:	Slingsby Partners LLP 1 Kingsway London WC2B 6AN (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 1 August 2016 refusing European patent application No. 07716416.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	N. Obrovski

Summary of Facts and Submissions

I. The appeal was filed by the applicant against the Examining Division's decision to refuse European patent application No. 07716416.8 for lack of inventive step.

II. In this decision, the Examining Division held that claim 1 of the main request and of the first and second auxiliary requests did not involve an inventive step over the following document, regarded as being the closest prior art:

D5: B. P. Kovatchev *et al.*, "*Quantifying Temporal Glucose Variability in Diabetes via Continuous Glucose Monitoring: Mathematical Methods and Clinical Application*", Diabetes Technology & Therapeutics, vol. 7, no. 6, 2005, pages 849-862, XP055135886, ISSN: 1520-9156, DOI: 10.1089/dia.2005.7.849

III. In response to the Board's communication pursuant to Article 15(1) EPC, in which the Board had expressed its preliminary opinion, the appellant filed further third and fourth auxiliary requests with the submission dated 16 February 2022.

IV. Oral proceedings before the Board were held on 14 March 2022.

V. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of one of the main request or first or second auxiliary requests, which had all been re-filed with the statement of grounds of appeal, or on the basis of one

of the third or fourth auxiliary requests filed with the submission dated 16 February 2022.

VI. Claim 1 of the **main request** reads as follows:

"A system adapted to measure blood glucose variability, said system comprising:

an acquisition module for acquiring a plurality of blood glucose data points;

a processor programmed to:

transform the plurality of blood glucose data points from a blood glucose range to a transformed range according to a transforming function;

calculate a risk value for each of the transformed plurality of blood glucose data points; characterised by the processor being further programmed to:

calculate a plurality of risk range values, each based on a maximal risk value of at least two of the calculated risk values within a period of time with a predetermined duration;

calculate at least one composite risk range value based on a summation of a plurality of the calculated risk range values; and

define risk categories using cutoff points of composite risk range values and classifying the calculated composite risk range value into one of the risk categories; and

a display module adapted to display the risk category that the calculated composite risk range value is classified into."

VII. Claim 1 of the **first auxiliary request** reads as follows:

"A system adapted to measure blood glucose variability, said system comprising:

an acquisition module for acquiring a plurality of self-monitored blood glucose data points;

a processor programmed to:

transform the plurality of blood glucose data points from a blood glucose range to a transformed range according to a transforming function;

calculate a risk value for each of the transformed plurality of blood glucose data points;
characterised by the processor being further programmed to:

calculate a maximal hypoglycemic risk value for a plurality of the calculated risk values for each day as:

$$LR^{i} = \max(rl(x_1^i), rl(x_2^i),..., rl(x_{n_i}^i)) ,$$

where n_i is the number of readings for each day i and x^i_1, x^i_2, ..., x^i_{ni} are the n_i self-monitored blood glucose data points for each day i and $rl(x^i_{ni}))$ [sic] is the calculated risk value representing a risk of hypoglycemia for the transformed n_i self-monitored blood glucose data points for each day i;

calculate a maximal hyperglycemic risk value for a plurality of the calculated risk values for each day i as:

$$HR^{i} = \max(rh(x_1^i), rh(x_2^i),..., rh(x_{n_i}^i)) ,$$

where n_i is the number of readings for each day i and x^i_1, x^i_2, ..., x^i_{ni} are the n_i self-monitored blood glucose data points for each day i and $rh(x^i_{ni}))$ [sic] is the calculated risk value representing a risk of hyperglycemia for the transformed n_i self-monitored blood glucose data points for each day i;

calculate at least one composite risk range value based on a summation of LR^i and HR^i;

define risk categories using cutoff points of composite risk range values and classifying the calculated composite risk range value into one of the risk categories; and

a display module adapted to display the risk category that the calculated composite risk range value is classified into."

VIII. Claim 1 of the **second auxiliary request** reads as follows:

"A system adapted to measure blood glucose variability, said system comprising:

an acquisition module for acquiring a plurality of self-monitored blood glucose data points, wherein the plurality of self-monitored blood glucose data points span a period of at least one day;

a processor programmed to:

transform the plurality of blood glucose data points from a blood glucose range to a transformed range according to a transforming function, wherein the minimal and maximal values of the transformed range are -√10 and √10, respectively, wherein the transforming function is:

$$f(BG, \alpha, \beta, \gamma) = \gamma . [(\ln(BG))^{\alpha} - \beta],$$

where *BG* is a blood glucose value, (α, β, γ) = (1.026, 1.861, 1.794) if *BG* is measured in mM, and (α, β, γ) = (1.084, 5.381, 1.509) if *BG* is measured in mg/dl; calculate a risk value for each of the transformed plurality of blood glucose data points by:

defining a *BG* risk space, wherein the *BG* risk space is:

$$r(BG) = 10 . f(BG)^2;$$

defining a left branch of the *BG* risk space representing a risk of hypoglycemia as:

rl(*BG*) = *r*(*BG*) if *f*(*BG*) < 0 and 0 otherwise;

defining a right branch of the *BG* risk space representing a risk of hyperglycemia as:

rh(*BG*) = *r*(*BG*) if *f*(*BG*) > 0 and 0 otherwise; characterised by the processor being further programmed to:

calculate a maximal hypoglycemic risk value for the plurality of self-monitored blood glucose data points for each day as:

$$LR^i = \max(rl(x_1^i), rl(x_2^i), \ldots, rl(x_{n_i}^i)),$$

where n_i is the number of readings for each day *i* and x^i_1, x^i_2, ..., x^i_{ni} are the n_i self-monitored blood glucose data points for each day *i*;

calculate a maximal hyperglycemic risk value for the plurality of self-monitored blood glucose data points for each day *i* as:

$$HR^{i} = \max(rh(x_1^i), rh(x_2^i),..., rh(x_{n_i}^i)) ,$$

where n_i is the number of readings for each day *i* and x^i_1, x^i_2, ..., x^i_{ni} are the n_i self-monitored blood glucose data points for each day *i*;

calculate average daily risk range as:

$$ADRR = \frac{1}{M}\sum_{i=1}^{M}[LR^{i} + HR^{i}] ,$$

where the plurality of blood glucose data points are collected on days *i* = 1, 2, ... , *M*; and

define risk categories using cutoff points of average daily risk range values and classifying the calculated average daily risk range into one of the risk categories;

a display module adapted to display the risk category that the calculated average daily risk range is classified into."

IX. Claim 1 of the **third auxiliary request** differs from claim 1 of the second auxiliary request in that

the expression "at least one day" in the definition of the period spanned by the plurality of self-monitored blood glucose data points has been replaced with "a plurality of days" and in that

the expression "the number of readings for each day being a series of readings;" has been added after both clauses "where n_i is the number of readings (...) blood glucose data points for each day *i*;".

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

the expression "at least one day" in the definition of the period spanned by the plurality of self-monitored blood glucose data points has been replaced with "at least seven days" and in that

the following expression, highlighted by the Board below, has been added to the end of the claim so as to read:

"(...) a display module adapted to display the risk category that the calculated average daily risk range is classified into;

wherein the plurality of blood glucose data points includes at least three blood glucose data point readings per day."

XI. The present decision also refers to the following documents:

D1: B. P. Kovatchev *et al.*, "*Risk Analysis of Blood Glucose Data: A Quantitative Approach to Optimizing the Control of Insulin Dependent Diabetes*", Journal of Theoretical Medicine, vol. 3, no. 1, 2000, pages 1-10, XP009136223, ISSN: 1027-3662
D2: WO 01/72208 A2
D3: US 2003/0216628 A1
D4: US 2005/0209515 A1
D6: US 2005/0214892 A1

XII. The appellant's arguments, as far as they are relevant for the present decision, can be summarised as follows.

Main request and first auxiliary request – Article 84 EPC

Claim 1 of both the main and the first auxiliary requests was supported by the description as required by Article 84 EPC. In particular, it included all the features that were essential for carrying out the invention.

In fact, the whole invention relied on the calculation of a composite risk range value based on the *maximum* risk values reached by risk values calculated over certain periods of time - instead of, for example, their *average* as known in the art. The number of periods of time over which blood glucose data points had been collected or the number of the collected blood glucose data points were not essential. It was thus immaterial that claim 1 was silent on these aspects.

Moreover, from the term "composite" the person skilled in the art understood how to carry out the claimed summation of the calculated risk range values. In particular, it was implicit from claim 1 that the summation included, as described in the description, the risk range values calculated for all of the periods of time over which the blood glucose data points had been collected, in particular for all days *i* according to the first auxiliary request.

Admittance of the third and fourth auxiliary requests

The third and fourth auxiliary requests were filed in reaction to objections under Article 84 EPC that had been raised for the first time by the Board in its communication pursuant to Article 15(1) RPBA 2020.

The amendments made in claim 1 of these requests clearly limited claim 1 of the second auxiliary request in order to address the Board's objections. These amendments were not complex and did not raise any new issues. The third and fourth auxiliary requests should therefore be admitted into the appeal proceedings.

Second to fourth auxiliary requests - inventive step

The Examining Division incorrectly considered that claim 1 of the second auxiliary request lacked an inventive step over D5.

The subject-matter of claim 1 differed from the disclosure of D5 on account of the way the acquired blood glucose data points were processed to determine the measure of the blood glucose variability. Compared to D5, the blood glucose data points were first aggregated over successive periods with a duration of one day, instead of one hour. The maximum values LR^i and HR^i, and not the averages, of the hypo- and hyperglycemic risk values reached over each day i were determined. Then their sum $LR^i + HR^i$ was averaged over all of the days over which blood glucose data points had been collected to obtain the risk index ADRR, on the basis of which the risk category was eventually determined.

As demonstrated by the experimental validation studies reported in the description, these differences had the technical effect, and thus solved the technical problem, of providing an overall measure of the glucose variability (i.e. equally sensitive to both hypo- and hyperglycemic events) and a prediction of glycemic events that were better than, or at least alternative to, those used in D5.

The Examining Division acknowledged these differences. However, it considered them to be obvious to the person skilled in the art, which was incorrect. In particular, proceeding from D5, the person skilled in the art would not have calculated maximum risk values of blood glucose readings over the day instead of their hourly averages. This would have led to losing the information about the frequency and time extent of the low and high blood glucose extreme events occurring throughout the day, contrary to the aim of the risk analysis described in D5.

ADRR was already pertinent when calculated from blood glucose data points spanning a period of a few days only. Because claim 1 defined a system and not a method, it was in fact irrelevant for the question of inventive step that claim 1 did not stipulate a specific number of blood glucose data points. It was sufficient that the claimed system was suitable for determining a better - or alternative - measure of blood glucose variability in those situations where an appropriate set of blood glucose data points was used, which the reported validation studies had established was the case for blood glucose data points spanning a period of one month or more.

It followed that the subject-matter of claim 1 of the second auxiliary request involved an inventive step over D5.

In the third and fourth auxiliary requests, claim 1 defined a specific minimum period of time spanned by the collected blood glucose data points and a specific minimum number of blood glucose readings collected per day. The subject-matter of these claims was therefore

further limited and, for this reason, it also involved an inventive step over D5.

Reasons for the Decision

1. The invention

1.1 In addition to average glycemia, blood glucose variability across low and high blood glucose values is an important parameter in diabetes management, especially in view of the risks associated with hypoglycemic events and the long-term complications, for example cardiovascular, due to hyperglycemia. Monitoring this parameter may help patients to improve their behaviour and self-treatment practices to reduce the risk of future severe hypo- and hyperglycemic excursions. This may also allow the effectiveness of therapies to be assessed (pages 4 and 43-44 of the description of the patent application).

1.2 For this purpose, the patent application provides a system for measuring blood glucose variability. This system comprises an acquisition module for acquiring a plurality of blood glucose data points over a plurality of predetermined time periods, for example over a number *M* of days; a processor programmed to calculate a risk index based on the acquired blood glucose data points and to classify it into a risk category; and a display module to display the determined risk category.

1.3 An algorithm to calculate the risk index from the acquired blood glucose data points is presented generally on page 11 of the description as filed and in more detail on pages 15-20. It comprises in essence the following steps:

- first, each of the n_i blood glucose data points acquired over day i, i.e. each x^i_j with $j = 1 \ldots n_i$, is transformed into a normalised value to compensate for the asymmetric nature of the blood glucose concentration scale;
- for each normalised blood glucose data point, a hypoglycemic risk value $rl(x^i_j)$ and a hyperglycemic risk value $rh(x^i_j)$ are calculated using a predetermined risk function, such as a parabolic function;
- maximal hypo- and hyperglycemic risk values LR^i and HR^i are then calculated for each day i respectively as the maximum of the risk values $rl(x^i_j)$ and $rh(x^i_j)$ reached over this day i;
- finally, an average daily risk range index (ADRR) is calculated as the average of $LR^i + HR^i$ over the M days over which blood glucose data points have been acquired. The application also discloses an alternative index (SDRR) calculated as the standard deviation of $LR^i + HR^i$ instead of its average (page 18, point 3.2).

As supported by experimental validation studies (see the correlation analyses reported in Tables 2 and 4A-4C of the description), this risk index ADRR, when calculated from a sufficiently large set of blood glucose data points spanning a sufficiently long period of time, turns out to be equally predictive of both low and high blood glucose excursions (see conclusions on pages 6 and 7). Hence, ADRR appears to be a reliable measure of the overall blood glucose variability, i.e. predictive of both hypoglycemia and hyperglycemia, especially compared to other measures of variability previously used (such as LBGI and HBGI or their sum; see page 22). Similar conclusions apply to the other index SDRR.

2. Main request and first auxiliary request - lack of support in the description (Article 84 CBE)

2.1 While the maximal hypoglycemic and hyperglycemic risk values LR^i and HR^i - explicitly defined in the first auxiliary request and corresponding to the "risk range values" in the main request - are determined as maximal risk values reached over each period of time with a predetermined duration, or each day i, the description consistently discloses that the risk index - called "composite risk range value" in these requests - must ultimately be calculated by a further aggregation of these maxima over a certain number M of periods of time - hence, the summation over i by means of which the average or the standard deviation is calculated to obtain ADRR or SDRR (see point 1.3 above).

It is true that in the mathematical description of the algorithm on page 11 the summation may in principle extend over one day only (line 4: "at least one day") - in which case the summation would be limited to one single term (i.e. $M = 1$).

However, from the description as a whole, the person skilled in the art understands that, in practice, a two-level data aggregation of the collected blood glucose data points, first within each period of time via the determination of the maximal risk values, then at a higher time scale via a further summation over a sufficiently large number M of periods of time, is essential to compute a composite risk range value that is meaningful and useful. In particular, the experimental validation results presented in the description have been systematically carried out with a data collection period of one month or even more (page 21, line 7; page 25, line 8; page 46, line 9;

page 47, line 18; page 53, line 19). Similarly, the exemplary data collection periods indicated in the description as appropriate are all longer than "about 7 [days]" (page 17, lines 1-4), for example "2-6 weeks" (page 8, line 16) or even ">2 months" (page 47, line 18). This is also already reflected in the very first paragraph of the section entitled "Brief summary of invention" (page 7), which mentions an overall period of blood glucose monitoring of "2-6 weeks" with blood glucose readings collected "3-5 times per day".

2.2 By contrast, claim 1 of both the main request and the first auxiliary request merely specifies calculating "at least one composite risk range value" based on "a summation of a plurality of the calculated risk range values" (main request) or "a summation of LR^i and HR^i" (first auxiliary request).

While the "calculated risk range values" as well as LR^i and HR^i do involve the determination of maximal risk values reached respectively over various periods of time, such as various days i, the wording of both claims leaves open how the summation is carried out. In particular, they do not specify which of the plurality of the "calculated risk range values" are included in the summation, or over which days i the summation extends.

The appellant's argument that the summation would implicitly extend over all days over which blood glucose data points have been collected does not convince the Board. Indeed, the expression "a summation of a plurality of the calculated risk range values" merely requires that the terms of the summation involve any subset of two or more of the various calculated risk range values, without any consideration of time.

The same applies to the expression "a summation of LR^i and HR^i", which does not exclude that the summation be limited to a subset of the days over which blood glucose data points have been collected, possibly a very small one. This is further supported by the fact that "at least one" composite risk range value is calculated, which does not exclude that several composite risk range values are calculated, each based on a summation carried out over a different, small set of periods of time or days *i*.

Moreover, none of the claims require a particular minimum number of periods of time, or days, over which blood glucose data points are collected. Thus, even if the appellant's argument above were accepted, calculating the composite risk range value from data points acquired over only one period of time would result in no further aggregation of the maxima occurring at a higher time scale, contrary to what is derived from the description as a whole to be an essential feature of the algorithm, as discussed in point 2.1 above.

The term "composite", which the appellant pointed out, does not necessary shed light on these time issues because it can simply mean that several types of glycemic risks are taken into account in the calculation, such as the hypoglycemic and hyperglycemic risks defined explicitly in the first auxiliary request.

2.3 In view of the above, it follows that, contrary to the appellant's submission, claim 1 of the main request and claim 1 of the first auxiliary request lack at least one feature that, from a proper consideration of the description, appears to be essential to calculating the

risk index in accordance with the invention. The Board thus concludes that claim 1 of the main request and claim 1 of the first auxiliary request are not supported by the description, contrary to the requirements of Article 84 EPC.

3. Second auxiliary request - inventive step

3.1 D5 was regarded as the closest prior art by the Examining Division. This document discloses a statistical risk analysis to quantify the blood glucose variability of a diabetic patient from self-monitored blood glucose data points. These data points are acquired over several days (for example, three days; see Figure 3), normalised and associated to hypo- and hyperglycemic risk values using a risk function (page 852, bottom of the left-hand column). They are then aggregated in one-hour intervals to calculate several risk indexes, such as the LBGI and HBGI indexes and their sum (page 852, top of the left-hand and right-hand columns). Thus, the risk for hypo- and hyperglycemia can be analysed over time.

3.2 The appellant argued that the subject-matter of claim 1 of the second auxiliary request was inventive over the disclosure of D5, contrary to the Examining Division's finding, on account of the way the acquired blood glucose data points were processed to derive a measure of the blood glucose variability. In particular, the appellant referred to the following features of claim 1, which define how the average daily risk range (ADRR) is calculated from the risk values determined for the plurality of self-monitored blood glucose data points:

(a) the periods of time over which the acquired blood glucose data points are first aggregated (by determining the maximum risk values reached over these periods as defined in (b) below) have a predetermined duration of *one day*, and not *one hour* as disclosed in D5 (page 852, top of the right-hand column, first line: "1-h set of CGM readings");

(b) for each period of time *i* (i.e. each day *i*), risk range values are calculated as the respective *maximal* hypo- and hyperglycemic risk values LR^i and HR^i reached over this period of time *i*, and not as the *average* risk values over this period as for LBGI and HBGI (see the formulas at the top of the right-hand column on page 852);

(c) the risk index ADRR is then calculated by *further averaging the sum* $LR^i + HR^i$ *over a number M of days* over which blood glucose data points have been collected, i.e. for *i* ranging from 1 to *M*.

3.2.2 The Board agrees that these features distinguish the subject-matter of claim 1 from the disclosure of D5. This was also accepted by the Examining Division in the decision under appeal (see point 17.2.4 in combination with points 16.2.2 and 15.3.1).

3.2.3 As acknowledged by the appellant, features (a)-(c) relate solely to the algorithm used in the claimed system to process the acquired blood glucose data points. These features, when taken in isolation, are non-technical. As such, they can support the presence of an inventive step only if they credibly contribute to producing a technical effect serving a technical purpose (*Case Law of the Boards of Appeal*, 9th edition, 2019, I.D.9.1.3 c)).

3.2.4 The appellant submitted that these features had the technical effect of providing an overall measure of the glucose variability (i.e. equally sensitive to both hypo- and hyperglycemic events) and a prediction of glycemic events that were better than, or at least alternative to, those used in D5.

3.2.5 While this effect does appear to be achieved for longer periods of observation, as in the experimental validation studies reported in the description, the Board does not find it credible that it is achieved if a very small number of blood glucose data points is used to calculate ADRR, in particular when the minimum number of blood glucose data points required by claim 1 is used, i.e. two data points spanning a period of one day only; see the discussion in point 2.1 above, especially the last paragraph. The appellant did not provide any convincing arguments demonstrating that this was the case.

3.2.6 It follows that, at least for these parts of the claimed subject-matter, features (a)-(c) do not contribute to the technical character of the claimed subject-matter and therefore cannot support the presence of an inventive step.

Contrary to the appellant's contention, it is irrelevant that features (a)-(c) might contribute to the technical character of the claimed subject-matter and thus to an inventive step for other parts of the claimed subject-matter, in particular when more blood glucose data points are used. A prerequisite for meeting the requirement that the claimed invention is inventive over the whole scope of the claim is indeed that it is also technical over the whole scope. The

requirement has not been met, as features (a)-(c) contribute to the technical character only for certain specific embodiments of the claimed invention (see G 1/19, Reasons 84).

The fact that claim 1 defines a system and not a method, as put forward by the appellant, is immaterial. Indeed, claim 1 does not merely require that the system be suitable for calculating ADRR from a higher number of blood glucose data points. Rather, the minimum number of blood glucose data points used to calculate ADRR is a feature of the algorithm specifically programmed in the processor of the claimed system. It is also a feature of the acquisition module, which must be specifically adapted to acquire at least this number of blood glucose data points. Thus, this minimum number is a feature of the claimed system itself.

3.3 The Examining Division considered that the further features distinguishing the subject-matter of claim 1 of the second auxiliary request from the disclosure of D5 would have been obvious to the person skilled in the art starting from this document (see decision under appeal, point 17.2.2 in combination with point 15.4.2).

The Board does not see any reason to deviate from this finding, especially in the absence of any counter-argument in this respect from the appellant.

3.4 The Board therefore concludes that the subject-matter of claim 1 of the second auxiliary request does not involve an inventive step over D5.

4. Admittance of the third and fourth auxiliary requests

4.1 The admittance of the third and fourth auxiliary requests is subject to Article 13(2) RPBA 2020, according to which any amendment to the appellant's appeal case made after notification of a summons to oral proceedings must, in principle, not be taken into account unless there are exceptional circumstances which have been justified with cogent reasons by the appellant.

4.2 The appellant filed these requests in reaction to new objections under Article 84 EPC that the Board had raised for the first time in its communication pursuant to Article 15(1) RPBA 2020, especially against the second auxiliary request. The amendments made in claim 1 of these requests clearly address these objections in limiting the scope of claim 1 of the second auxiliary request in a manner consistent with what the Board had indicated seemed to be patentable. These amendments were not complex and did not raise new issues.

4.3 For these reasons, the Board considered that exceptional circumstances within the meaning of Article 13(2) RPBA 2020 applied and therefore decided to admit the third and fourth requests into the proceedings.

5. Third auxiliary request - inventive step

5.1 Compared to claim 1 of the second auxiliary request, claim 1 of the third auxiliary request includes the limitations that the plurality of self-monitored blood glucose data points span a period of "a plurality of days", i.e. at least two days, and that "a series of readings" is acquired for each day, i.e. at least two readings.

5.2 Hence, claim 1 of the third auxiliary request encompasses a system in which ADRR is calculated from only four blood glucose data points spanning a period of two days.

For the same reasons as discussed above in respect of the second auxiliary request (see point 3.2.5 above), the Board is not convinced that, for so few blood glucose data points collected over only two days, features (a)-(c) can support the presence of an inventive step. It follows that the subject-matter of claim 1 of the third auxiliary request does not involve an inventive step over D5 either.

6. Fourth auxiliary request

6.1 Articles 84 and 123(2) EPC

6.1.1 The subject-matter of claim 1 of the fourth auxiliary request is based on the system described on page 11 of the description as filed, with the further limitations that the plurality of self-monitored blood glucose data points span a period of "at least seven days", and that "at least three blood glucose data point readings" are acquired for each day.

In the first sentence of page 17, the description as filed discloses explicitly a number n_i of blood glucose readings "greater than or equal to 3" for each day i. In the next sentence, it discloses several ranges for the number of days over which blood glucose data points are collected, all including at least seven days. Even if upper bounds are mentioned, the person skilled in the art understands, in the light of the description as a whole, that it is the lower bound (thus, a minimum of about seven days) that matters to lend to the

calculated index ADRR a sufficiently high reliability (see point 2.1 above). The disclosure of upper bounds appears instead to be linked to inherent technical limitations of the system, for example, in terms of memory and processing capabilities (page 31, line 5).

The Board is therefore satisfied that the subject-matter of claim 1 of the fourth auxiliary request does not contain added subject-matter. Accordingly, the requirements of Article 123(2) EPC are met.

6.1.2 The Board is also convinced that claim 1 is clear and supported by the description. In particular, the objection raised against to the main and first auxiliary requests (see point 2. above) does not apply to claim 1 of the fourth auxiliary request. The Board is thus satisfied that the requirements of Article 84 EPC are also met.

6.2 Inventive step

6.2.1 Claim 1 of the fourth auxiliary request requires a minimum of 3 x 7 = 21 data points spanning a period of seven days. Even though this corresponds to a smaller set of data points than used in the experimental validations studies reported in the description (see point 2.1 above), the Board finds it credible that this number of blood glucose data points and the period they span still represent a sufficiently large sample to be statistically significant. The Board is therefore satisfied that, in these conditions, the technical effect put forward by the appellant (point 3.2.4 above) is achieved over the whole claimed subject-matter. Accordingly, features (a)-(c) can *a priori* support the presence of an inventive step.

6.2.2 The Board concurs with the appellant's view that, contrary to the Examining Division's view (point 15.4.1 of the decision under appeal), the person skilled in the art, starting from D5, would have had no motivation to modify the definition of LBGI and HBGI given in D5 so as to determine *maximum* risk values instead of *average* risk values (feature (a)).

Indeed, as disclosed in D5, page 852, top of the left-hand column, the risk indices LBGI and HBGI have been specifically constructed so as to be a "measure of the frequency and extent" of the low and high blood glucose readings, respectively. Replacing the *average* risk value averaged over each period of time by the *maximum* value reached over said period would erase information on the frequency and extent of the blood glucose excursions occurring during that period of time, as argued by the appellant. This would be contrary to the purpose of the risk analysis presented in D5. Without the benefit of hindsight, the person skilled in the art would have therefore not envisaged such a modification.

Moreover, none of the other documents D1-D4 and D6 cited in the decision under appeal discloses or suggests feature (a).

At least for this reason, the subject-matter of claim 1 of the fourth auxiliary request involves an inventive step over D5, contrary to the Examining Division's finding.

6.2.3 The same conclusion holds when applying the problem-solution approach starting from the other documents cited in the decision under appeal.

The algorithm to carry out the risk analysis described in D1 is also based on the summation of LBGI and HBGI (page 3, left-hand column, first paragraph, last sentence; page 5, formulas at the top of right-hand column), and is thus based on calculating *averages* of the hypo- and hyperglycemic risk values over a period of time of a predetermined duration, not determining the *maximum* risk values reached over this period.

For the same reasons as discussed above for D5, the person skilled in the art, starting from D1, would have had no motivation to modify the algorithm so as to arrive at the subject-matter of claim 1.

Furthermore, none of D2-D4 and D6 discloses or suggests a risk index calculated with the two-fold data aggregation defined in claim 1.

6.2.4 The Board therefore concludes that the subject-matter of claim 1 of the fourth auxiliary request involves an inventive step, contrary to the Examining Division's finding.

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 with the order to grant a patent on the basis of claims 1-16 of the fourth auxiliary request filed with the submission dated 16 February 2022 and a description to be adapted.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated