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**Datasheet for the decision  
of 8 May 2019**

**Case Number:** T 2576/17 - 3.2.02

**Application Number:** 12170112.2

**Publication Number:** 2494922

**IPC:** A61B5/145, A61B5/1495,  
A61B5/1486, G01N27/327

**Language of the proceedings:** EN

**Title of invention:**  
Processing analyte sensor data

**Applicant:**  
DexCom, Inc.

**Headword:**

**Relevant legal provisions:**  
EPC Art. 56, 111(1)

**Keyword:**  
Inventive step - (yes)  
Appeal decision - remittal to the department of first instance  
(yes)

**Decisions cited:**  
T 0683/12, T 2549/17, T 2578/17

**Catchword:**



**Beschwerdekammern**  
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Case Number: T 2576/17 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 8 May 2019**

**Appellant:** DexCom, Inc.  
(Applicant) 6340 Sequence Drive  
San Diego CA 92121 (US)

**Representative:** Hill, Justin John  
Dentons UKMEA LLP  
One Fleet Place  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 14 July 2017  
refusing European patent application No.  
12170112.2 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** S. Böttcher  
M. Stern

## **Summary of Facts and Submissions**

- I. The applicant lodged an appeal against the decision of the Examining Division to refuse European patent application No. 12170112.2 because the subject-matter of claims 1 and 12 then on file was found to lack inventive step over D2 = WO-A-00/49941 in combination with D1 = Clarke W. et al: "Evaluating Clinical Accuracy of Systems for Self-Monitoring of Blood Glucose", Diabetes Care, American Diabetes Association, Vol. 10, No. 5, September-October 1987, pages 622 to 627.
- II. The present case is related to the cases underlying decisions T 2578/17 and T 2549/17, as well as T 683/12.
- III. Notice of appeal was received on 8 September 2017. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 10 November 2017.
- IV. 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 and the first auxiliary request, both filed with the statement of grounds of appeal. Oral proceedings were also requested.
- V. With a communication dated 28 November 2018, the appellant was informed that the Board intended to set aside the decision and to remit the case to the department of first instance for further prosecution.
- VI. By letter of 11 December 2018, the appellant announced that it conditionally withdrew its request for oral proceedings subject to the remittance to the department

of first instance.

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

"A method for evaluating clinical acceptability of reference data in a substantially continuous glucose monitoring system prior to accepting the data as valid entries to be processed by the substantially continuous glucose monitoring system, the method including: receiving a data stream from a substantially continuous analyte sensor, including one or more sensor data points; receiving reference data from a reference analyte monitor, including one or more reference data points; and evaluating the clinical acceptability of the reference data with respect to substantially time corresponding sensor data points, wherein the reference data is evaluated for deviation from its substantially time corresponding sensor data, and wherein the evaluating the clinical acceptability further comprises using a clinical risk associated with that deviation based on the glucose value indicated by the reference data."

VIII. Claim 12 of the main request reads as follows:

"A system for evaluating clinical acceptability of reference data in a substantially continuous glucose monitoring system, the system adapted to: receive a data stream from a substantially continuous analyte sensor, including one or more sensor data points; receive reference data from a reference analyte monitor, including one or more reference data points; and

evaluate the clinical acceptability of the reference data with respect to substantially time corresponding sensor data points prior to accepting the data as valid entries to be processed by the substantially continuous glucose monitoring system, wherein the reference data is evaluated for deviation from its substantially time corresponding sensor data, and wherein the evaluation of the clinical acceptability further comprises use of a clinical risk associated with that deviation based on the glucose value indicated by the reference data."

- IX. The appellant's arguments are essentially those on which the following reasons for this decision are based.

### **Reasons for the Decision**

1. The appeal is admissible.
2. Subject-matter of the application

The application relates to a method (claim 1) and a system (claim 12) for evaluating clinical acceptability of reference data in a glucose monitoring system. Although not explicitly mentioned in the claims, the reference data is used for calibrating the glucose monitoring system.

The method of claim 1 is described in paragraphs [0362] to [0365] of the description, and illustrated in the flow chart in Figure 8.

An implanted glucose monitoring system needs to be calibrated. In order to obtain reference data for

calibration, the user may perform a self-test by obtaining a blood sample from their finger and analysing this sample using a reference glucose monitor. This reference measurement may be erroneous, e.g. in case the user has traces of sugar on their finger. Hence, according to the claimed method, the reference data is compared to data obtained by the implanted sensor, and the clinical acceptability of the reference value is evaluated on the basis of the deviation of the reference value from its time corresponding sensor value.

The result of the evaluation can then be used to control the user interface. If the reference data is not clinically acceptable, a fail-safe mode is started and the user is prompted to provide an updated reference analyte value. The updated value is then used to calibrate the implanted sensor.

Hence, with the claimed method, the calibration of the implanted sensor may be improved.

Claim 12 defines the corresponding device.

3. Inventive step - Article 56 EPC

D2 relates to glucose monitoring systems and the calibration thereof. As in the present application, reference glucose values are used to calibrate the sensor data (page 17, line 23 to page 18, line 24). Hence, as correctly stated by the Examining Division, D2 discloses the steps of receiving sensor data and receiving reference data.

However, D2 does not address the clinical acceptability of the reference data. On the contrary, it is mentioned

in D2 that the reference data is assumed to be accurate (page 18, lines 4 to 8).

Thus, D2 does not disclose the step "evaluating the clinical acceptability of the reference data...".

The problem to be solved by the present invention is to improve the calibration process.

Evaluating the clinical acceptability of reference glucose data is not known from D1 either. D1 discloses evaluating the clinical accuracy of self-monitoring blood glucose systems. As described on page 623, right-hand column, paragraph headed "methods", to page 624, right-hand column, first paragraph, the blood glucose values of various systems (Eyetone, Dextrometer, Glucometer,...) are compared to reference values, e.g. whole blood glucose values measured with a glucose analyzer. Hence, also in D1 the reference values are deemed to be correct. D1 does not disclose the evaluation of the clinical acceptability of *reference data*, and therefore, the combination of D2 and D1 does not render the subject-matter of claim 1 obvious.

Consequently, the Board considers the subject-matter of claim 1 to involve an inventive step.

Claim 12 relates to the corresponding system for continuously evaluating the quality of a calibration of an analyte sensor. For the same reasons that apply to claim 1, its subject-matter therefore involves an inventive step.

4. As the claims of the main request have not been examined with regard to the other requirements of the EPC (in particular clarity and sufficiency of



disclosure), the case is remitted to the Examining Division for further prosecution pursuant to Article 111(1) EPC.

## Order

### For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated