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

**Case Number:** T 2578/17 - 3.2.02

**Application Number:** 12170105.6

**Publication Number:** 2497415

**IPC:** A61B5/00, G01N31/00, A61B5/145,  
G01N27/327, A61B5/1495,  
A61B5/1486

**Language of the proceedings:** EN

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

**Applicant:**  
DexCom, Inc.

**Headword:**

**Relevant legal provisions:**  
EPC Art. 54, 111(1)

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

**Decisions cited:**

T 0683/12, T 2549/17, T 2576/17

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
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Case Number: T 2578/17 - 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 17 July 2017  
refusing European patent application No.  
12170105.6 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. 12170105.6 because the subject-matter of claims 1 and 2 then on file was found to lack novelty over D1 = WO-A-00/49941.
- II. The present case is related to the cases underlying decisions T 2576/17 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 13 November 2017.
- IV. The appellant requested that the decision under appeal be set aside and that the application be remitted for grant of a patent on the basis of the main request filed with the statement of grounds of appeal. It also requested oral proceedings.
- 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 continuously evaluating the quality of a

calibration of an analyte sensor after subcutaneous implementation into a user, the method including: receiving a data stream from an analyte sensor, including one or more sensor data points; receiving reference data from a reference analyte monitor, including two or more reference data points; providing at least two matched data pairs by matching reference analyte data to substantially time corresponding sensor data; forming a calibration set including the at least two matching data pairs; creating a conversion function based on the calibration set; receiving additional sensor data from the analyte sensor; converting sensor data into calibrated data using conversion function; and evaluating the quality of matched data pairs in the calibration set used to create the conversion function using one of linear regression, non-linear regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference."

VIII. Claim 2 of the main request reads as follows:

"A system for continuously evaluating the quality of a calibration of an analyte sensor after subcutaneous implementation into a user, the system including: means for receiving a data stream from an analyte sensor, including one or more sensor data points; means for receiving reference data from a reference analyte monitor, including two or more reference data points; means for providing at least two matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

means for forming a calibration set including the at least two matching data pairs;  
means for creating a conversion function based on the calibration set;  
means for receiving additional sensor data from the analyte sensor;  
means for converting sensor data into calibrated data using the conversion function; and  
means for evaluating the quality of matched data pairs in the calibration set used to create the conversion function using linear regression, non-linear regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference."

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 2) for evaluating the quality of a calibration of an analyte sensor (i.e. a glucose sensor which is implanted subcutaneously).

The method of claim 1 is described in paragraphs [0382] to [0410] of the description, and illustrated in the flow charts in Figures 10 and 11.

In order to calibrate the implanted sensor, sensor data is matched with corresponding reference data from a reference sensor to build matched data pairs. At least two of these data pairs form a calibration set that is used to calculate a conversion function. This conversion function is then employed to convert any further sensor data into calibrated data. The quality of this calibration is determined based on the association of the calibration set data using statistical analysis, i.e. one of the association functions mentioned in the claim. In essence, it is evaluated how well the data points fit to the regression line (Figs. 12A and 12B).

The result of the quality evaluation can then be used to control the user interface. If the calibration is not deemed sufficient in quality, a fail-safe mode is started and the user is prompted to provide an updated reference analyte value. With the updated value the conversion function is also updated and then again evaluated for statistical accuracy (paragraphs [0409] to [0410]).

Hence, with the claimed method the safety and accuracy of the analyte monitoring may be enhanced.

3. Novelty - Article 54 EPC

D1 relates to calibration methods for glucose monitors. In detail, paired calibration data points are established by temporally correlating a blood glucose reference value to a value measured by the glucose monitor (page 17, line 27 to page 18, line 10). These paired calibration data points correspond to the matched data pairs mentioned in claim 1. A plurality of these matched data pairs is used to calculate a

conversion function (best fit straight line, page 22, last paragraph, Figs. 14 and 15). The slope of the line is the linear regression sensitivity ratio (LRSR), which is then used to calibrate further sensor data.

D1 further discloses calculating a modified LRSR (MLRSR) for particular glucose sensors. The MLRSR is compared to a valid sensitivity range to determine if it is reasonable and to generate a calibration error alarm if it is not reasonable (page 23, line 17 to page 24, line 20). This process can be regarded as a method for evaluating the quality of a calibration.

However, it is not the statistical association of the data pairs which is evaluated, and the evaluation does not use one of linear regression, non-linear regression, rank correlation, least mean square fit, etc., as is claimed.

D1 merely describes using linear regression for calculating the MLRSR, i.e. the slope of the regression line. This MLRSR value is then checked for plausibility. However, there is no disclosure in D1 of a step of evaluating the quality of the matched data pairs applied to the linear regression.

Thus, the subject-matter of claim 1 is novel over D1 since D1 fails to disclose the step "evaluating the quality of matched data pairs in the calibration set used to create the conversion function using one of linear regression, non-linear regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference".

Claim 2 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 is therefore also novel over D1.

4. As the claims of the main request have not been examined with regard to the other requirements of the EPC (in particular clarity, added subject-matter and inventive step), the case is remitted to the Examining Division for further prosecution pursuant to Article 111(1) EPC, as requested by the appellant.

## 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