



(51) International Patent Classification:

G01N 27/327 (2006.01) A61B 5/157 (2006.01)
A61B 5/145 (2006.01)

(21) International Application Number:

PCT/US2023/085495

(22) International Filing Date:

21 December 2023 (21.12.2023)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/434,833 22 December 2022 (22.12.2022) US

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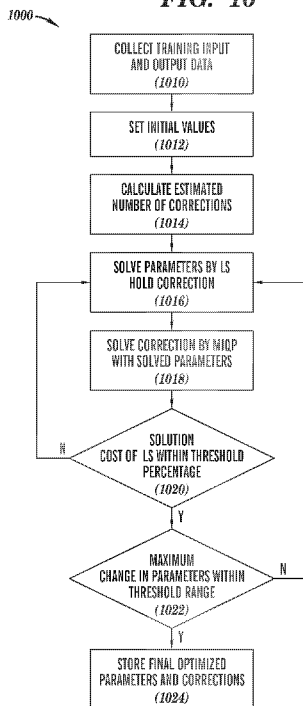
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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, MG, MK, MN, MU, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, CV, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE,

(54) Title: MODEL IDENTIFICATION WITH INCOMPLETE INPUT DATA IN TYPE I DIABETES

FIG. 10



(57) Abstract: A system and method for identifying an individualized glucose dynamics model for managing glucose of a patient is disclosed. The method includes collecting glucose concentration output data from the patient over a period of time. Carbohydrate size and insulin infusion input data is collected from the patient over the period of time. Parameters of a glucose dynamics model are optimized via solving an iterative optimization problem such as a nonlinear least squares problem based on the collected data while fixing a constant time and amount of a correction value. The time and amount of a modified correction value are determined based on executing a mixed integer quadratic program on the collected data while fixing a constant value for the parameters of the glucose dynamics model. A final correction value and final optimized parameters of the model are provided based on iterating the optimizing parameters and determining the modified correction value.

WO 2024/138024 A3

SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:

25 July 2024 (25.07.2024)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US23/85495

<p>A. CLASSIFICATION OF SUBJECT MATTER</p> <p>IPC - INV. G01N 27/327 (2023.01) ADD. A61B 5/145; A61B 5/157 (2023.01) CPC - INV. A61B 5/14532; G01N 27/3271 ADD. A61B 5/14503; A61B 5/157; A61M 2230/201</p> <p>According to International Patent Classification (IPC) or to both national classification and IPC</p>																		
<p>B. FIELDS SEARCHED</p> <p>Minimum documentation searched (classification system followed by classification symbols) See Search History document</p> <p>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched See Search History document</p> <p>Electronic database consulted during the international search (name of database and, where practicable, search terms used) See Search History document</p>																		
<p>C. DOCUMENTS CONSIDERED TO BE RELEVANT</p> <table border="1"> <thead> <tr> <th>Category*</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>X</td> <td>US 2021/0369149 A1 (DEXCOM INC.) 02 December 2021; Paragraphs [0260-0283], [0420]</td> <td>1-23</td> </tr> <tr> <td>A</td> <td>WO 2015/021441 A1 (ALERE SAN DIEGO INC.) 12 February 2015; Entire document</td> <td>1-23</td> </tr> <tr> <td>A</td> <td>US 2014/0039823 A1 (NEXTNAV LLC) 06 February 2014; Paragraphs [0122], [0190-0192], [0212], [0225]</td> <td>1-23</td> </tr> </tbody> </table> <p><input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.</p> <p>* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "D" document cited by the applicant in the international application "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family</p> <table border="1"> <tr> <td>Date of the actual completion of the international search 30 April 2024 (30.04.2024)</td> <td>Date of mailing of the international search report MAY 30 2024</td> </tr> <tr> <td>Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300</td> <td>Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300</td> </tr> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	X	US 2021/0369149 A1 (DEXCOM INC.) 02 December 2021; Paragraphs [0260-0283], [0420]	1-23	A	WO 2015/021441 A1 (ALERE SAN DIEGO INC.) 12 February 2015; Entire document	1-23	A	US 2014/0039823 A1 (NEXTNAV LLC) 06 February 2014; Paragraphs [0122], [0190-0192], [0212], [0225]	1-23	Date of the actual completion of the international search 30 April 2024 (30.04.2024)	Date of mailing of the international search report MAY 30 2024	Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US23/85495

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
-***-Please See Supplemental Page-***-

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-23

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US23/85495

-Continued From Box No. III: Observations where unity of invention is lacking-

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fee must be paid.

Group I: Claims 1-23 are directed toward a method for determining a modified dynamic model.

Group II: Claims 24-38 are directed toward a system for managing glucose of a patient.

The special technical features of Group I include at least providing a final correction value and final optimized parameters to the dynamic system model from iterating the optimizing the parameters of the dynamic system model and determining the modified correction value.

The special technical features of Group II include at least accept a carbohydrate size input from the patient; accept an insulin infusion input from the patient; modify the carbohydrate size input with a correction value of an individualized glucose dynamics model including optimized parameters, wherein the correction value and optimized parameters are determined; provide the insulin infusion input and the modified carbohydrate size input to the individualized glucose dynamics model to determine a prediction of glucose outcome; and send a command to the insulin pump to deliver a determined insulin dosage based on the predicted glucose outcome.

The common technical features shared by Groups I & II are collecting output data over a period of time; collecting input data over a period of time; optimizing parameters of a dynamic system model via solving a nonlinear least squares problem based on the collected data while fixing a correction value; determining a modified correction value based on a mixed integer quadratic program executed on the collected data while fixing a constant value for the parameters of the model. However, these common features are previously disclosed by US 2014/0039823 A1 to NextNav, LLC (hereinafter "NextNav"). NextNav discloses collecting output data over a period of time (sensor outputs; [0225]); collecting input data over a period of time (input reference sensor data; [0212]); optimizing parameters of a dynamic system model via solving a nonlinear least squares problem based on the collected data while fixing a correction value (nonlinear and least squares method; [0190-0192] & [0318]); determining a modified correction value based on a mixed integer quadratic program executed on the collected data while fixing a constant value for the parameters of the model (correction value wherein values are solved by quadratic interpolation; [0122]; Claims 24 & 27).

Since the common technical features are previously disclosed by the NextNav reference, these common features are not special and so Groups I-II lack unity.