UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/699,989	09/08/2017	Anna Leigh Davis	DEXCOM.379C1	1065

68851 7590 06/07/2021

KNOBBE, MARTENS, OLSON & BEAR, LLP
DEXCOM, INC.
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER
BARR, MARY EVANGELINE

ART UNIT	PAPER NUMBER
3626	

NOTIFICATION DATE	DELIVERY MODE
06/07/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efiling@knobbe.com
jayna.cartee@knobbe.com

Office Action Summary	Application No. 15/699,989	Applicant(s) Davis et al.	
	Examiner Evangeline Barr	Art Unit 3626	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 04/26/2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-4,6-14 and 27-31 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-4,6-14 and 27-31 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/26/2021 has been entered.

Status of the Application

3. **Claims 1-4, 6-14 and 27-31** are currently pending in this case and have been examined and addressed below. This communication is a Non-Final Rejection in response to the Amendment to the Claims and Remarks filed on 04/26/2021.

- **Claims 1-4, 6-7, 10, 12, and 29** have been amended.
- **Claims 5 and 15-26** are cancelled and not considered at this time.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

5. **Claims 1-4, 6-14 and 27-31** are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 12 recite generating an expected glucose pattern based on one or more bolus value calculations calculated based on the one or more bolus calculator parameters by utilizing computational intelligence including one or more of neural network-based mapping, fuzzy logic based pattern matching, or genetic-algorithms based pattern matching to extrapolate forward the expected glucose pattern. However, there is no support in the specification or other disclosure for the concept of generating an expected glucose pattern, and there is no support for utilizing computational intelligence including any of neural network-based mapping, fuzzy logic based pattern matching, or genetic-algorithms based pattern matching for determining the expected glucose pattern. The specification does describe reviewing historical data to determine if patterns are present ([0217]), but the pattern is not described as being an expected glucose pattern but merely described this as a post-event pattern quantification, without describing whether the event is historical or expected, and therefore, the pattern does not equate to an expected pattern. Additionally, the specification does not disclose any use of neural network-based mapping, fuzzy logic based pattern matching or genetic-algorithms based pattern matching, and thus does not support the use of one of these analyses to extrapolate forward an expected glucose pattern. The specification includes

that data such as patterns of data is mined for data that may be useful in modification of bolus calculator settings ([0221]), but this does not include the types of analysis of the claims or extrapolating using the analysis types to determine an expected pattern.

As per **Claims 2-4, 6-11, 13-14 and 27-31**, the claims depend on Claims 1 and 12 and do not remedy the written description requirement issues of Claims 1 and 12. As dependent claims inherit the deficiencies of the claims they depend on, they are also rejected.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. **Claims 1-4, 6-14 and 27-31** are rejected because the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more. Claims 1-4, 6-14 and 27-31 are directed to the abstract idea of a health care provider setting up a bolus calculator which falls into the grouping of certain methods of organizing human activity including managing personal behavior such as teaching or following instructions.

As per Claims 1 and 12, the limitations of displaying or transmitting for display a fillable form, as drafted, is a step executed by a device that, under its broadest reasonable interpretation, covers managing personal behavior or interactions between people including following rules or instructions but for the recitation of generic computer components. The limitation of configuring the bolus calculator at the device using the one or more bolus calculator parameters also includes managing personal behavior or interactions such as a

person setting up a bolus calculator on a device. Similarly, the limitations of determining or detecting a bolus calculator parameter/setting change triggering event indicative of a need for modifying bolus calculator parameters and transmitting a notification to the HCP about the triggering event, as drafted, under its broadest reasonable interpretation, covers certain methods of organizing human activity which includes managing personal behavior or interactions between people including teaching and following rules or instructions. A user interacts with the information to make the determination regarding a parameter/setting change and in response interacts with the HCP to notify them about the event. The claims also recite displaying an approval prompt and upon acceptance of the approval prompt, modifying bolus calculator parameters which, under its broadest reasonable interpretation, covers managing personal behaviors or interactions between people. The patient accepts the approval prompt and this interaction triggers the following of the rules to modify the parameters. As per the *October 2019 Update on Subject Matter Eligibility*, the certain methods of organizing human activity grouping of abstract ideas includes sub-groupings which encompass both activity of a single person and activity that involves multiple people, and thus certain activity between a person and a computer may fall within the certain methods of organizing human activity grouping. The transmitting for display a fillable form for a user to enter bolus calculator parameters in the fields includes a user interaction with a computer. Additionally, determining or detecting a bolus calculator parameter change triggering event has occurred and transmitting a notification involves a user interacting with the information that is received and displayed, which is certain activity between a person and a computer. The displaying an approval prompt, acceptance of the prompt are also examples of certain activity between a

person and a computer. The modifying bolus calculator parameters involves following rules or instructions on how the modification to the parameters is to be made. If a claim limitation, under its broadest reasonable interpretation, covers managing personal behavior or relationships or interactions between people including teaching and following rules or instructions, but for the recitation of generic computer components, then it falls within the "Certain Methods of Organizing Human Behavior" grouping of abstract ideas. The bolus calculator is not positively recited in the claim, but the claim recites using the calculator to calculate a bolus value based on input to the bolus calculator. The calculating of bolus values based on input falls into the mental processes and the mathematical concepts groupings of abstract ideas. The claims do not limit what method is used to calculate the bolus value and therefore, using the bolus calculator parameters to calculate a bolus value can be done using a concept which can be done in the human mind by use of observation, evaluation and judgement or it could be calculated using a mathematical calculation to determine the value. Because the claim element can fall into either the mental processes or mathematical concepts grouping, the claim limitation is abstract. The claims recite generating an expected glucose pattern based on bolus value calculations calculated based on the one or more bolus calculator parameters, determining or detecting a bolus calculator parameter change triggering event indicative of a need for modifying the bolus calculator parameters in response to identifying a threshold amount of deviation from the expected glucose pattern and determining the deviation is addressable by a change in the one or more bolus calculator parameters, and determining modified bolus calculator parameters based on the change triggering event which are activities which can be performed in the human mind. Using human evaluation, judgement,

opinion and observation, a person can generate an expected glucose pattern based on bolus value calculations and determine change triggering events in response to identifying a threshold amount of deviation from the expected pattern. A person could mentally determine that the deviation can be addressed by a change in the bolus calculator parameters and then determine modified parameters. Because the claim elements can fall into the mental processes grouping, the claim limitations are abstract. Accordingly, the claim recites an abstract idea.

This judicial exception is not integrated into a practical application because the additional elements and combination of additional elements do not impose meaningful limits on the judicial exception. In particular, the claim recites the additional elements – a server for login, receiving data, and determining triggering events; a health care provider (HCP) device for communicating, transmitting and receiving data with the server and displaying information; a patient device for receiving data and executing the features of the abstract idea, receiving data from the fillable form; and transmitting data to a device. The server is recited at a high-level of generality such that it amounts to no more than mere instructions to apply the exception using a generic computer component. Accordingly, this additional element does not integrate the abstract idea into a practical application because it does not impose any meaningful limits on practicing the abstract idea. The claim does not positively recite the bolus calculator itself, but using the calculator to calculate a bolus value is also mere instructions to apply the exception. The bolus calculator is described in the specification as an application ([0018]) running on a patient device such as a smartphone ([0053]). This is an example of the additional element being mere instructions to apply the exception because they do no more than merely invoke computers of machinery as a tool to perform a process such as a mathematical algorithm being

applied on a general purpose computer, as per MPEP 2106.05(f)(2)(i), where the patient device is shown to be a general purpose computer device such as a smartphone as above, or tablet or wearable device ([0007], Fig. 1A). The HCP device for communicating with the server and displaying information also is described in the specification as a general purpose computer component such as a PC, tablet, etc. ([00142], see Fig. 4) such that it amounts to mere instructions to apply the exception for the same reasons as the patient device. The claim also includes utilizing computational intelligence including neural network-based mapping, fuzzy logic or genetic-algorithms based pattern matching to generate an expected pattern, where the generation of an expected glucose pattern recites a mental process as it can be practically performed in the human mind, as described above. The use of a mathematical algorithm such as any of the recited algorithms, which are recited at a high-level of generality, to apply to the abstract idea of generating an expected pattern amounts to mere instructions to apply the exception. As per MPEP 2106.05(f), a claim that recites only the idea of a solution or outcome and fails to recite details of how a solution to a problem is accomplished and use of computers as a tool to perform existing processes such as a commonplace mathematical algorithm applied on a general purpose computer, has been found by the courts to amount to mere instructions to apply the exception and does not integrate the abstract idea into a practical application or provide significantly more. The claim also recites the additional elements of the receiving data from the fillable form and transmitting data to a device which are insignificant extra-solution activity, as in as in MPEP 2106.05(g), because the steps of receiving data and transmitting data is mere data gathering in conjunction with the abstract idea where the limitation amounts to necessary data gathering and outputting, (*i.e.*, all uses of the recited judicial exception require

such data gathering or data output). See *Mayo*, 566 U.S. at 79, 101 USPQ2d at 1968; *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1363, 115 USPQ2d 1090, 1092-93 (Fed. Cir. 2015) (presenting offers and gathering statistics amounted to mere data gathering). Because the additional elements do not impose meaningful limitations on the judicial exception, the claim is directed to an abstract idea.

The claims do not include additional elements that are sufficient to amount to significantly more than the judicial exception. As discussed above with respect to integration of the abstract idea into a practical application, the additional elements of a server amounts to no more than mere instructions to apply the exception using a generic computer component. These elements recite a generic computing system by reciting an Internet server, router, computer, smartphone, etc. (Specification, [00109]), which do not add meaningful limitations to the abstract idea beyond mere instructions to apply an exception. Additionally, the bolus calculator is recited as an application running on a patient device such as a smartphone ([0053]). The claims recite utilizing computational intelligence including neural network-based mapping, fuzzy logic or genetic-algorithms based pattern matching to generate an expected pattern which as described above amounts to mere instructions to apply the exception because it applies a mathematical algorithm to the abstract idea of generating an expected glucose pattern. The specification only describes the mathematical algorithm at a high level of generality including the system determines a post event pattern quantification. As discussed above, the system is a general purpose computer which carries out the computational intelligence. As computation intelligence can be a computer function which includes performing repetitive calculations that a general purpose computer is capable of executing, the

function is considered to be well-understood, routine and conventional, similar to MPEP 2106.05(d)(II)(ii). Mere instructions to apply an exception using a generic computer component cannot provide an inventive concept. The additional elements of receiving data from the fillable form and transmitting data to a device amount to insignificant extra-solution activity, as described above, which are elements that are well-understood, routine and conventional computer functions because they are claimed at a high level of generality and include receiving or transmitting data, which has been found to be well-understood, routine and convention computer functions by the Court (MPEP 2106.05(d)(II)(i) Receiving or transmitting data over a network, *e.g.*, using the Internet to gather data, *Symantec*, 838 F.3d at 1321, 120 USPQ2d at 1362 (utilizing an intermediary computer to forward information); *TLI Communications LLC v. AV Auto. LLC*, 823 F.3d 607, 610, 118 USPQ2d 1744, 1745 (Fed. Cir. 2016) (using a telephone for image transmission); *OIP Techs., Inc., v. Amazon.com, Inc.*, 788 F.3d 1359, 1363, 115 USPQ2d 1090, 1093 (Fed. Cir. 2015) (sending messages over a network); *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350, 1355, 112 USPQ2d 1093, 1096 (Fed. Cir. 2014) (computer receives and sends information over a network); but see *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1258, 113 USPQ2d 1097, 1106 (Fed. Cir. 2014) ("Unlike the claims in *Ultramercial*, the claims at issue here specify ***how*** interactions with the Internet are manipulated to yield a desired result--a result that overrides the routine and conventional sequence of events ordinarily triggered by the click of a hyperlink." (emphasis added)). Looking at the limitations as an ordered combination adds nothing that is not already present when looking at the elements taken individually. There is no indication that the combination of elements improves the functioning

of the computer or improves another technology. The claims do not amount to significantly more than the underlying abstract idea.

Dependent claims 2-4, 6-11, 13-14 and 27-31 add additional limitations. The dependent claims include limitations which further specify or limit the elements of the independent claims, and hence are nonetheless directed towards fundamentally the same abstract idea. Claim 2 includes prioritizing or ranking the triggering events which, similar to the independent claim, is a method of organizing human activity because the user follows rules or instructions based on the received data. Claims 27 and 28 further specify that the bolus value is calculated according to received values. As described in the independent claims, the calculating of the bolus value is not limited to a particular way of calculation and thus it could fall into either the mental processes or mathematical concepts abstract idea grouping. The limitations of the remaining dependent claims only serve to further limit or specify the limitations of the independent claims, and hence are nonetheless directed towards fundamentally the same abstract idea as independent claims 1 and 12.

The dependent claims do not include additional elements that integrate the abstract idea into a practical application. The dependent claims include additional elements similar to the independent claims including transmitting a subset of prioritized events to the HCP, receiving a modification and transmitting the modification to a device which are insignificant extra-solution activity, as in MPEP 2106.05(g), because the steps amounts to necessary data gathering and outputting, (*i.e.*, all uses of the recited judicial exception require such data gathering or data output). See *Mayo*, 566 U.S. at 79, 101 USPQ2d at 1968; *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1363, 115 USPQ2d 1090, 1092-93 (Fed. Cir. 2015) (presenting

offers and gathering statistics amounted to mere data gathering). Because the additional elements do not impose meaningful limitations on the judicial exception, the claim is directed to an abstract idea. Accordingly, the additional elements do not integrate the abstract idea into a practical application because it does not impose any meaningful limits on practicing the abstract idea.

The additional elements of the dependent claims do not include additional elements that are sufficient to amount to significantly more than the judicial exception. As discussed above, the steps of transmitting a subset of prioritized events to the HCP, receiving a modification and transmitting the modification to a device are insignificant extra-solution activity which is no more than well-understood, routine, conventional activities previously known to the industry including mere data gathering similar to performing clinical tests on individuals to obtain input for an equation, *In re Grams,* 888 F.2d 835, 839-40; 12 USPQ2d 1824, 1827-28 (Fed. Cir. 1989) as per MPEP 2106.05(g). As the additional elements are well-understood, routine and conventional functionalities in the art, the claims do not amount to significantly more than the abstract idea and are not patent eligible.

In view of the foregoing, claims 1-4, 6-14 and 27-31 do not amount to significantly more than the above-identified abstract idea and are accordingly rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter.

Response to Arguments

8. Applicant's arguments, see Pages 9-11, "Discussion of Claim Rejections Under 35 U.S.C. §101", filed 04/26/2021 with respect to claims 1-4, 6-14 and 27-31 have been fully considered but they are not persuasive.

Applicant argues that the present claims cannot practically be performed in the human mind because a human cannot mentally generate an expected glucose pattern utilizing computational intelligence including one or more of neural network-based mapping, fuzzy logic based and genetic-algorithm based pattern matching. Examiner respectfully disagrees that the claims are not directed to an abstract idea because they do not fall into the grouping of a mental process. A human can mentally evaluate the bolus value calculations to generate an expected glucose pattern. This is directed to the abstract idea of a mental process. The utilization of computational intelligence does no more than merely invoke computers or machinery as a tool to perform the abstract idea, which is the generation of the expected pattern. As per MPEP 2106.05(f)(2), the use of a mathematical algorithm applied on a general purpose computer has been found by the courts to be an additional element which amounts to mere instructions to apply the exception. As per the 101 rejection above, the method of the claims is carried out by a general purpose computer. Computational intelligence is the functional capability of the computer, and as the computer is a general purpose computer this does not integrate the abstract idea into a practical application or provide significantly more than the abstract idea. The neural network-based mapping, fuzzy logic based pattern matching, or genetic-algorithms based pattern matching are claimed as already developed mathematical algorithms applied by the general purpose computer and thus are mere instructions to apply the exception.

Examiner notes that as per the Examiner Interview summary of 04/19/2021, the inclusion of an algorithm which does not include more than utilizing a known type of mathematical analysis or a known algorithm would simply be mere instructions to apply the

exception and would not be sufficient in overcoming the 101 rejection. However, inclusion of generation of a particular algorithm which is used to generate an output and use of the output would be considered for furthering prosecution in terms of subject matter eligibility. As the present claims are applying mathematical algorithms recited at a high level of generality, the 101 rejection is maintained.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yodfat et al. (US 2019/0099551 A1) discloses a system and method for diabetes management which includes a controller which includes a bolus calculator and receives settings data from a health care provider including insulin sensitivity index and carb factor through a user interface and is stored in the controller for use in the bolus calculator ([0094], Fig. 37).

Brukalo et al. (US 2008/0312512 A1) discloses bolus calculator setup in which data is input on a remote controller device and when devices are paired, the settings such as carbohydrate ratio are copied to the device, i.e. patient device, and these calculator settings are used by the bolus calculator to determine bolus value (Fig. 16A/B, [0066]).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evangeline Barr whose telephone number is (571)272-0369. The examiner can normally be reached on Monday to Friday 8:00 am to 4:00 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is

encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fonya Long can be reached on 571-270-5096. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EVANGELINE BARR/
Primary Examiner, Art Unit 3626

REMARKS

Claims 1, 6, and 12 are amended. Claim 4 is canceled, without prejudice. The amendments are supported at least by the Specification at paras. 19, 26, 69, 71 (including incorporated by reference U.S. Patent Publication No. 2007/0208246 at para 517, 638, and 692), 117, 219, and 229.

112 Rejection Comments

Claims 1-4, 6-14, and 27-31 stand rejected under 35 U.S.C. § 112(a), or 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. Though Applicant does not necessarily agree with the rejections under § 112, Applicant has amended the claims herein to expedite prosecution and respectfully submits that the amended claims are supported by the Specification as filed and therefore satisfy the requirements of §112.

For example, each of claim 1 and 12 recites:

"generating estimated glucose concentration values for a future time period based on one or more real-time glucose concentration values measured by a continuous glucose monitor associated with the patient by utilizing computational intelligence including one or more of neural network-based mapping, fuzzy logic based pattern matching, or genetic-algorithms based pattern matching to extrapolate forward the estimated glucose concentration values for the future time period; [and] determining or detecting, in real-time, a bolus calculator parameter change triggering event based on the estimated glucose concentration values for the future time period indicating a clinical risk alert, wherein the clinical risk alert is addressable by a change in the one or more bolus calculator parameters."

The Specification at para. [0069] discusses that: "[i]n certain embodiments, each of the alerts is associated with one or more actions that are to be performed in response to triggering of the alert[, and that]. ... [a]lerts may also result in a bolus calculator parameter/setting modification trigger being activated, and a consequent signal being generated and transmitted to an HCP server, as described in greater detail below." Therefore the Specification supports that a bolus calculator parameter change triggering event can be based on an alert.

The Specification at para. [0071] further discusses that "U.S. Patent Publication No. 2007/0208246, which is incorporated herein by reference in its entirety, describes some systems and methods associated with the clinical risk alerts (or alarms) described herein," meaning that the clinical risk alerts of the incorporated by reference '246 Publication are a type of alert that can be the basis for a bolus calculator parameter change triggering event.

The incorporated '246 Publication at para. 517 describes that: "In alternative embodiments, the conversion function is used to predict analyte values at future points in time. These predicted values can be used to alert the user of upcoming hypoglycemic or hyperglycemic events." The incorporated '246 Publication at para. 692 describes that: "In contrast to alarms that prompt or alert a patient when a measured or projected analyte value or rate of change simply passes a predetermined threshold, the clinical risk alarms of the preferred embodiments combine intelligent and dynamic estimative algorithms to provide greater accuracy, more timeliness in pending danger, avoidance of false alarms, and less annoyance for the patient. In general, clinical risk alarms of the preferred embodiments include dynamic and intelligent estimative algorithms based on analyte value, rate of change, acceleration, clinical risk, statistical probabilities, known physiological constraints, and/or individual physiological patterns, thereby providing more appropriate, clinically safe, and patient-friendly alarms." Therefore, the incorporated '246 Publication supports that clinical risk alerts can be on the basis of predicted or projected analyte (e.g., glucose) values.

The incorporated '246 Publication at para. 638 describes that: "Generally, algorithms that estimate analyte values from measured analyte values include any algorithm that fits the measured analyte values to a pattern, and/or extrapolates estimated values for another time period (for example, for a future time period or for a time period during which data needs to be replaced). ... In some alternative embodiments, computational intelligence (for example, neural network-based mapping, fuzzy logic based pattern matching, genetic-algorithms based pattern matching, or the like) can be used to fit measured analyte values to a pattern, and/or extrapolate forward." Therefore, the incorporated '246 Publication supports that the predicted or projected analyte values used to determine the clinical risk alert can be determined by utilizing computational intelligence including one or more of neural network-based mapping, fuzzy logic based pattern matching, or genetic-algorithms based pattern matching to extrapolate forward the estimated glucose concentration values for the future time period.

The Specification at para. 19 describes that: "Where the bolus calculator parameters/setting change triggering event include a detected pattern, the pattern detected may be via an analysis of CGM traces. The pattern may be one that is remediable by a change in bolus calculator parameters/settings." The Specification at para. 219 further describes that: "However it is determined that the bolus calculator parameters/settings are sub optimal, more optimal or improved parameters may be determined (step **914**)." Therefore, the Specification supports that the bolus calculator parameters may be changed to address sub optimality, which as discussed can be determined in view of a clinical risk alert.

The Specification at para. 229 describes that: "Generally, the above systems and methods use historical data, including inferred quantities such as patterns, to inform a real-time present suggestion or change to a parameter or setting of a bolus calculator. While the determination of the change or modification is at least in part automatic, implementation of the change itself may be subject to confirmation by the patient, HCP, or both." Therefore, the Specification supports that the bolus calculator parameters change is triggered and occurs in real-time.

Accordingly, Applicant respectfully submits that the amended claim features of claim 1 and 12, and the remaining claims dependent thereon, satisfy the requirements of § 112, and requests that the rejections under § 112 be withdrawn.

101 Rejection Discussion

Claims 1-4, 6-14, and 27-31 stand rejected under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter. Office Action, pgs. 4-5. Applicant respectfully traverses this rejection.

The Office Action, in part, alleges that "determining or detecting a bolus calculator parameter change triggering event ... can be performed in the human mind." *OA*, p. 6-7. However, Applicant respectfully submits that such features of amended claim 1 cannot be performed in the human mind, and therefore do not recite an abstract idea. Further, the features of amended claim 1 provide an improvement to the technical field of bolus calculation by triggering bolus calculation based on real-time data, which cannot be performed mentally or by humans without a machine, which allows for more frequent updating of bolus calculator parameters to improve glucose levels in a patient.

Claim 1, as amended, recites "generating estimated glucose concentration values for a future time period based on one or more real-time glucose concentration values measured by a continuous glucose monitor associated with the patient by utilizing computational intelligence including one or more of neural network-based mapping, fuzzy logic based pattern matching, or genetic-algorithms based pattern matching to extrapolate forward the estimated glucose concentration values for the future time period; [and] determining or detecting, in real-time, a bolus calculator parameter change triggering event based on the estimated glucose concentration values for the future time period indicating a clinical risk alert, wherein the clinical risk alert is addressable by a change in the one or more bolus calculator parameters". Applicant submits that amended claim 1 is allowable for the following reasons.

Applicant has amended claim 1 to clarify how the bolus calculator parameters are modified such that the modification process cannot be performed in the human mind or by pen and paper. In particular, claim 1 generates estimated glucose concentration values for a future time period based on one or more *real-time* glucose concentration values measured by a continuous glucose monitor associated with the patient by utilizing computational intelligence including one or more of neural network-based mapping, fuzzy logic based pattern matching, or genetic-algorithms based pattern matching to extrapolate forward the estimated glucose concentration values for the future time period that cannot be conceivably performed in the mind. In particular, a human is incapable of being able to estimate in real-time future glucose concentration values using the complex functions required, as it would simply take too long for a human to do that in real time. Further, a human would also not be able to use such estimated glucose concentration values in real time to determine a bolus calculator parameter change triggering event, as since a human cannot determine the estimated values in real time mentally, the human would be incapable of using the estimated glucose concentration values in real time mentally to determine the bolus calculator parameter change triggering event. Thus, Applicant submits the complex analysis in real time of the data to determine the estimated glucose concentration values and use of such values in real time to determine the bolus calculator parameter change triggering event, a recited in claim 1, cannot be performed in the human mind or by pen and paper in real time, and therefore claim 1 is not directed to an abstract idea.

In addition, the Specification describes how such real time analysis of the data to determine the estimated glucose concentration values and use of such values in real time to

determine the bolus calculator parameter change triggering event provide an improvement to the technical field of glucose management, therefore integrating, *arguendo*, any abstract idea into a practical application thus making claim 1 subject matter eligible. For example, para. 216, 219, and 229 discuss how sub optimal parameters for the bolus calculator may be improved, which may beneficially keep a user's glucose level within a target range. Performing such tasks in a real time manner through the use of a continuous glucose monitor and the specific functions claimed may help to keep a user's glucose level within a target range, even as conditions change for the user. Para. 54 even describes the problem of how "[w]hile a significant amount of prior art has been developed in the context of bolus calculators, particularly among pump manufacturers, the same is generally related to calculations and dosing on the basis of SMBG measurements, not continuous glucose monitoring measurements, nor on the many important properties and information derivable there from." Paras. 12 and 59 describe the benefit of the claimed solution being "more frequent, updates to bolus calculator parameters as may be needed, to "hone in" on a best set of parameters or to determine the best set of parameters for a given situation of the patient, e.g., weekends versus weekdays."

Claim 12 recites substantially similar elements to claim 1. Thus, Applicant submits that claims 1 and 12 and their dependent claims are allowable and requests withdrawal of all § 101 rejections with respect to these claims.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 27, 2021

By:/Heungsoo Choi/
Heungsoo Choi
Registration No. 69,282
Registered Practitioner
(949) 290-8044

AMENDMENTS TO THE CLAIMS

1. (**Currently Amended**) A method for enabling health care provider (HCP) set up of a bolus calculator, comprising:

upon login by an HCP to a server using an HCP device associated with the HCP, displaying at the HCP device, or transmitting from the server to the HCP device for display at the HCP device, a fillable form, the fillable form including one or more fields for entry of one or more bolus calculator parameters;

receiving, at the server from the HCP device, data provided by the HCP in the fillable form, the data corresponding to the one or more bolus calculator parameters;

upon login by a patient to the server, transmitting data, at the server, to a device associated with the patient, the transmitted data based on the received data, where the transmitted data corresponds to the one or more bolus calculator parameters in a format suitable for configuration of the bolus calculator executing on the device, wherein the one or more bolus calculator parameters are used by the device to configure the bolus calculator at the device, the bolus calculator used by the device to calculate a bolus value based on input to the bolus calculator that is then processed by the bolus calculator, configured according to the one or more bolus calculator parameters, to calculate the bolus value;

generating ~~an expected~~ estimated glucose ~~pattern~~ concentration values for a future time period based on one or more real-time glucose concentration values measured by a continuous glucose monitor associated with the patient ~~one or more bolus value calculations calculated based on the one or more bolus calculator parameters~~ by utilizing computational intelligence including one or more of neural network-based mapping, fuzzy logic based pattern matching, or genetic-algorithms based pattern matching to extrapolate forward the ~~expected~~ estimated glucose concentration values for the future time period~~pattern~~;

determining or detecting, in real-time, a bolus calculator parameter change triggering event based on the estimated glucose concentration values for the future time period indicating a clinical risk alert, ~~indicative of a need for modifying at least one of the one or more bolus calculator parameters in response to identifying~~ wherein the clinical risk alert ~~a threshold amount~~

~~of deviation from the expected glucose pattern~~ ~~and determining that the deviation~~ is addressable by a change in the one or more bolus calculator parameters;

based on the bolus calculator parameter change triggering event, automatically determining modified bolus calculator parameters; and

at least one of transmitting a notification to the HCP about the modified bolus calculator parameter change triggering event or transmitting the modified bolus calculator parameters to the device.

2. (Previously Presented) The method of Claim 1, wherein the determining or detecting comprises determining or detecting multiple bolus calculator parameter change triggering events including the bolus calculator parameter change triggering event, and further comprising prioritizing or ranking the multiple bolus calculator parameter change triggering events before transmitting the notification to the HCP.

3. (Previously Presented) The method of Claim 2, further comprising transmitting a subset of the prioritized or ranked bolus calculator parameter change triggering events to the HCP, the subset including the bolus calculator parameter change triggering event.

4. (**Canceled**)

5. (Canceled)

6. (**Currently Amended**) The method of Claim 1 [[4]], wherein the bolus calculator parameter change triggering event is further in response to [[the]] a detected pattern of the one or more real-time glucose concentration values comprising ~~includes~~ at least one of nighttime lows or post-prandial highs.

7. (Previously Presented) The method of Claim 1, wherein the bolus calculator parameter change triggering event is based on an atypical glucose response.

8. (Previously Presented) The method of Claim 1, further comprising receiving a modification to the one or more bolus calculator parameters in response to the notification to the HCP, and transmitting the modification to the device associated with the patient.

9. (Previously Presented) The method of Claim 8, wherein the modification adjusts a basal rate or the at least one of the one or more bolus calculator parameters.

10. (Previously Presented) The method of Claim 1, wherein the bolus calculator parameter change triggering event is further in response to detection of at least occasional departures in one or more actual bolus values administered as compared to the one or more bolus value calculations.

11. (Previously Presented) The method of Claim 10, wherein the departures are of the same sign and value, and wherein the departure values are within a common range.

12. (**Currently Amended**) A method for enabling health care provider (HCP) set up of a bolus calculator, comprising:

upon login by an HCP to a server using an HCP device associated with the HCP, displaying at the HCP device, or transmitting from the server to the HCP device for display at the HCP device, a fillable form, the fillable form including one or more fields for entry of one or more bolus calculator parameters;

receiving, at the server from the HCP device, data provided by the HCP in the fillable form, the data corresponding to the one or more bolus calculator parameters;

upon login by a patient to the server, transmitting data, at the server, to a device associated with the patient, the transmitted data based on the received data, wherein the transmitted data corresponds to the one or more bolus calculator parameters in a format suitable for configuration of the bolus calculator executing on the device, wherein the one or more bolus calculator parameters are used by the device to configure the bolus calculator at the device, the bolus calculator used by the device to calculate a bolus value based on input to the bolus

calculator that is then processed by the bolus calculator, configured according to the one or more bolus calculator parameters, to calculate the bolus value;

generating ~~an expected~~ estimated glucose ~~pattern~~ concentration values for a future time period based on one or more real-time glucose concentration values measured by a continuous glucose monitor associated with the patient ~~one or more bolus value calculations calculated based on the one or more bolus calculator parameters~~ by utilizing computational intelligence including one or more of neural network-based mapping, fuzzy logic based pattern matching, or genetic-algorithms based pattern matching to extrapolate forward the ~~expected~~ estimated glucose concentration values for the future time period~~pattern~~;

determining or detecting, in real-time, a bolus calculator parameter change triggering event based on the estimated glucose concentration values for the future time period indicating a clinical risk alert, ~~indicative of a need for modifying at least one of the one or more bolus calculator parameters in response to identifying a~~ wherein the clinical risk alert ~~threshold amount of deviation from the expected glucose pattern and determining that the deviation~~ is addressable by a change in the one or more bolus calculator parameters;

based on the bolus calculator parameter change triggering event, automatically determining modified bolus calculator parameters; and

on the device associated with the patient, receiving an indication of modification to the one or more bolus calculator parameters based on the modified bolus calculator parameters, and displaying an approval prompt on a user interface of the device to determine whether the patient approves the modification to the one or more bolus calculator parameters, and upon acceptance of the approval prompt, automatically modifying the one or more bolus calculator parameters based on the modification.

13. (Previously Presented) The method of Claim 12, wherein the one or more bolus calculator parameters entered by the HCP are specific to a range of time within a day, or are specific to weekdays versus weekends.

14. (Previously Presented) The method of Claim 12, wherein the form is displayed to the HCP with pre-populated data obtained from user account data or from data associated with a medical device.

15-26. (Canceled)

27. (Previously Presented) The method of claim 1, wherein the input to the bolus calculator comprises one or more values received at the device from one or more sensors or input mechanisms different from the HCP.

28. (Previously Presented) The method of claim 12, wherein the input to the bolus calculator comprises one or more values received at the device from one or more sensors or input mechanisms different from the HCP.

29. (Previously Presented) The method of claim 1, wherein the triggering event is based on at least one of: a repeated pattern of user modifications to the one or more bolus values calculations, an atypical glucose response, at least occasional departures in one or more actual bolus values administered as compared to the one or more bolus value calculations, and a detected pattern of glucose measurements.

30. (Previously Presented) The method of claim 12, wherein the one or more bolus calculator parameters comprise one or more of a carbohydrate count, fat intake, protein intake, meal size, insulin-to-carb ratio (ICR), glucose targets, glucose thresholds, insulin action times, and glucose trends.

31. (Previously Presented) The method of claim 8, wherein the modification is within a range based on one or more of weight, history, age, and body mass index (BMI) of the patient.