



Algorithm for Diabetes Management and Control

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OTHER INFORMATION

KEYWORDS

indpharma, diabetes, insulin,

blood sugar, blood glucose,

Artificial Pancreas, health

monitoring

CATEGORIZED AS

- **Medical**
- Other

RELATED CASES

2016-315-0

BRIEF DESCRIPTION

A number of technologies have been developed that optimize the process of managing blood sugar and administering insulin.

BACKGROUND

With the increase of diabetes across the globe, accurate and automated administration of insulin to patients with type 1 diabetes is a major need. The Continuous Glucose Monitoring (CGM) market is growing, with the number of people diagnosed with type 1 diabetes on the rise globally. Safe and efficient software for CGM and Artificial Pancreas (AP) systems will be important for companies growing and competing in this field.

DESCRIPTION

This portfolio of technologies has been extensively developed in close collaboration with industry partners.

Additionally, the portfolio has been the subject of numerous successful patient/clinical trials (described below) and are protected by a comprehensive patent estate.

An Enhanced Model Predictive Control for the Artificial Pancreas Using a Confidence Index Based on

Residual Analysis of Past Predictions

UC Case no. 2016-315

An adaptive strategy for monitoring accurate glucose predictions that provides safe and effective glucose management and results in a significant reduction of hypoglycemia events. When compared to a static controller, this adaptive controller is able to avoid hypoglycemia more efficiently while the static controller has spurious episodes of hypoglycemia. [Learn more...](#)

Daily Periodic Target-Zone Modulation in the Model Predictive Control Problem for Artificial Pancreas for

Type 1 Diabetes Applications

UC Case no. 2013-384

A model predictive control (MPC) strategy to prevent a nocturnal hypoglycemic event using an Artificial Pancreas. The advantage of this MPC is that it employs periodic time- dependent target zones and insulin input constraints. This allows the safe operation of glycaemia controllers while the patient is sleeping and not able to intake glucose in the event of a hypoglycemic risk. This technology is covered by pending U.S. rights, as well as applications in EP, JP, KR, CH, CA and AU. [Learn more...](#)

Clinical Trials

Twelve-Week 24/7 Ambulatory Artificial Pancreas with Weekly Adaptation of Insulin Delivery Settings: Effect on Hemoglobin A_{1c} and Hypoglycemia

This approach has potential to remove the need for clinician involvement before or during use of the AP. Results show a statistical significant reduction in HbA_{1c} and hypoglycemia. This report shows a significant decrease of time in glucose <70 mg/dL and improvements in HbA_{1c}.

Application of Zone Model Predictive Control Artificial Pancreas during Extended Use or Infusion Set and Sensor

This project represents the first home-use AP study testing system to component failure through extended use while also testing the safety and efficacy of the AP system. Results show the AP system is superior with reduced median glucose values, increased time in the target range, and a decrease in hypoglycemia. AP improved percent time 70-140 mg/dL (48.1 vs. 39.2%; P=0.016) and time 70-180 mg/dL (71.6 vs. 65.2%; P=0.008) and decreased median glucose (141 vs. 153 mg/dL; P=0.036).

Adjustment of Open-Loop Settings to Improve Closed-Loop Results in type 1 Diabetes

This study looked at the effects of a one-time algorithmic adjustment of basal rate and insulin to carbohydrate ration open-loop settings on the performance of CLC. The CLC system proved robust and adaptable with minimal (<25%) time spent in the hypoglycemic range. The zone-MPC control algorithm eliminated nocturnal hypoglycemia. Median time in CLC was 25.3 hours. The median time in the 80-140mg/dl range was similar in both groups. Both groups showed minimal time spent less than 70 mg/dl (median 1.34% and 1.37%). There were no significant difference more than 140 mg/dl.

Outpatient Closed-Loop Control with Unannounced Moderate Exercise in Adolescents Using Zone Model Predictive Control

The first evaluation in adolescents of the Zone Model Predictive Control and Health Monitoring System (ZMPC+HMS) AP algorithms, and their first evaluation in a supervised outpatient setting with frequent exercise. The use of the ZMPC+HMS algorithms is feasible in the adolescent outpatient environment and achieved significantly more time in the desired glycemic range than sensor augmented pump (SAP) in the face of unannounced exercise and large announced meal challenges. The percentage of time with continuous glucose monitor (CGM) 70-180 mg/dL was 71% +/- 10% during CLC, compared to 57%+/- 16% during SAP. Nocturnal control during CPC was safe, with 0% of time with CGM<70mg/dL compared to 1.1% during SAP.

Clinical Evaluation of an Automated Artificial Pancreas Using Zone-Model Predictive Control and Health Monitoring System

This study was performed to evaluate the safety and efficacy of a fully automated artificial pancreas using zone-model predictive control (zone-MPC) with the health monitoring system (HMS) during announced meals and overnight and exercise periods. The combination of the zone-MPC controller and the HMS hypoglycemia prevention algorithm was able to safely regulate glucose in a tight range with no adverse events despite the challenges of unannounced meals and moderate exercise. The HMS sent appropriate warnings to prevent hypoglycemia via short and multimedia message services, at an average of 3.8 treatments per subject.

PATENT STATUS

Country	Type	Number	Dated	Case
United States Of America	Issued Patent	10,878,964	12/29/2020	2016-315

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