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SYMPOSIUM

Control to Range for Diabetes: Functionality and Modular Architecture

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Abstract

Background:

Closed-loop control of type 1 diabetes is receiving increasing attention due to advancement in glucose sensor and insulin pump technology. Here the function and structure of a class of control algorithms designed to exert control to range, defined as insulin treatment optimizing glycemia within a predefined target range by preventing extreme glucose fluctuations, are studied.

Methods:

The main contribution of the article is definition of a modular architecture for control to range. Emphasis is on system specifications rather than algorithmic realization. The key system architecture elements are two interacting modules: range correction module, which assesses the risk for incipient hyper- or hypoglycemia and adjusts insulin rate accordingly, and safety supervision module, which assesses the risk for hypoglycemia and attenuates or discontinues insulin delivery when necessary. The novel engineering concept of range correction module is that algorithm action is relative to a nominal open-loop strategy—a predefined combination of basal rate and boluses believed to be optimal under nominal conditions.

Results:

A proof of concept of the feasibility of our control-to-range strategy is illustrated by using a prototypal implementation tested *in silico* on patient use cases. These functional and architectural distinctions provide several advantages, including (i) significant insulin delivery corrections are only made if relevant risks are detected; (ii) drawbacks of integral action are avoided, e.g., undershoots with consequent hypoglycemic risks; (iii) a simple linear model is sufficient and complex algorithmic constraints are replaced by safety supervision; and (iv) the nominal profile provides straightforward individualization for each patient.

Conclusions:

We believe that the modular control-to-range system is the best approach to incremental development, regulatory approval, industrial deployment, and clinical acceptance of closed-loop control for diabetes.

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Abbreviations: (AP) artificial pancreas, (APS) artificial pancreas software, (BG) blood glucose, (CGM) continuous glucose monitoring, (MPC) model predictive control, (FDA) Food and Drug Administration, (IOB) insulin on board, (PID) proportional-integral-derivative, (RCM) range correction module, (SSM) safety supervisor module

Keywords: artificial pancreas, closed-loop control algorithms, continuous glucose monitoring, diabetes, modeling

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