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ORIGINAL ARTICLES

Modular Artificial β-Cell System: A Prototype for Clinical Research

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Abstract

Background:

The quest toward an artificial β-cell has been accelerating, propelled by recent technological advances in subcutaneous glucose sensors and insulin pumps. The development and clinical testing of algorithms involves several challenges: communication and data transfer between a sensor and a pump via computer, a human interface presenting real-time information to the physician, safety issues when an automated system is used to administer insulin, and an architecture that supports different sensors, pumps, and control algorithms. These challenges were addressed in the development of a modular artificial β-cell system for clinical research.

Methods:

The developmental environment of MATLAB® (The MathWorks, Inc., Natick, MA) allowed the flexible implementation of communication protocols for different sensors and pumps. The system has a plug-and-play option for the control algorithm and a human interface that presents and logs the data, enforces protocol safety rules, and facilitates physician oversight.

Results:

A novel platform for use in clinical research trials was realized as a bridge toward a portable unit. This prototype encapsulates communication between the control algorithm, the pump, and the sensors. Its intuitive human interface presents all the relevant patient information to the physician and allows events to be electronically logged. It facilitates subject safety by way of integrated interlocks, checklists, and alarms.

Conclusion:

The modular design of the system allows for the robust testing of various sensors and pumps as well as feedback control, meal detection, predictive hypoglycemia alarms, and device-related algorithms to detect sensor or pump failure.

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Abbreviations: (APS) artificial pancreas software, (BG) blood glucose, (CGM) continuous glucose monitor, (CRC) clinical research center, (CSII) continuous subcutaneous insulin infusion, (GUI) graphical user interface, (HMI) human–machine interface, (HPA) hypoglycemia prediction algorithm, (IrDA) infrared data association, (MPC) model predictive control, (PDM) personal diabetes manager, (PID) proportional-integrative-derivative, (PNP) plug-and-play, (RF) radio frequency, (RT) real time, (USB) universal serial bus

Keywords: type 1 diabetes mellitus, closed-loop control, artificial pancreas

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