OmniPod®
Insulin Management System

# CPT CORNER

*The Newsletter of Insulet Certified Pod Trainers* Wednesday, October 26, 2011

# Insulet's Role in Artificial Pancreas Research: Part 1

*Hope Warshaw, MMSc, RD, CDE, BC-ADM*

As a CPT trainer you're likely aware or have heard about research on the Artificial Pancreas Closed-Loop Systems (AP). But are you aware of Insulet's involvement in the AP research? We'll detail the history and update you on Insulet's ongoing engagement with AP research teams around the world. Thanks to key leaders on Insulet's AP team for sharing their expertise so I may share it with my fellow certified Pod trainers.

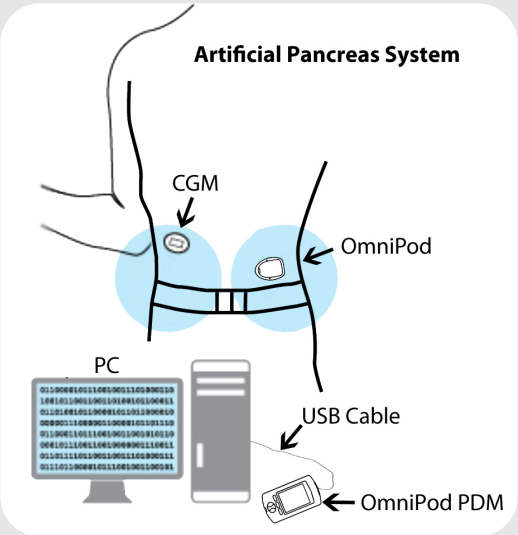
**Bits of the History**

Insulet's initial involvement began in 2006 with the AP research team at Sansum Diabetes Research Institute (Santa Barbara, CA). To meet their needs (and eventually many others), Insulet developed an AP-specific Personal Data Manager (PDM) known as the "Red PDM." These PDMs are used in combination with a Personal Computer (PC), or mobile device, which holds a control algorithm. Once operating and receiving CGM data, the control algorithm sends insulin delivery instructions to the "Red PDM," which instructs the Pod to deliver the insulin the algorithm is requesting.

Documentation for the AP-specific PDM was submitted to the FDA in the form of a master file and has many regulatory requirements, including verification and validation. AP researchers, through an FDA Investigational Device Exemption (IDE) submission, reference this master file document and can then use Insulet's technology in their studies.

**Fast Forward to Present**

Since 2006, Insulet has been working with numerous AP research teams globally. AP research goes way beyond a sophisticated understanding of diabetes management. It includes sorting out very complex control theory challenges. Teams typically include mathematicians, engineers (mechanical, chemical, software and electrical), medical professionals, diabetes educators and more.




Insulet's AP technology group continues to work on completing the next-generation AP platform. In addition to a lot of researcher feedback, the next-generation AP platform responds to the need to communicate with multiple Pods (e.g. to deliver both glucagon and insulin) as well as the capacity to receive Continuous Glucose Monitoring (CGM) data. This will eliminate the need for a CGM-specific receiver. The next-generation PDM is planned to be used in European studies starting later this year and U.S. studies in early 2012.

**Artificial Pancreas Models in Research**

Each research team is studying and evolving their uniquely tweaked AP model. However, the core elements have similarities: the controller, which directs the medication infusions based on unique algorithms, and a currently available FDA-approved sensor and delivery device (the Pods). The controller is the most critical and challenging element to develop – it's the "brain" of the system. Algorithms used to drive the controllers are developed based on a variety of control theories. One of the more popular theories is called model predictive control (MPC). MPC is based on mathematical modeling for complex and dynamically changing systems. Most of the controllers currently under investigation are operated from a PC. As AP research and technology evolves towards commercialization, the controller will likely be integrated into more portable devices, such as a smart phone.

AP research teams are applying two main trains of thought regarding infusion of medication(s) and blood glucose control. Several teams use an insulin-only approach. Others use a "bi-hormonal" approach with insulin in one Pod and glucagon in a second Pod. The OmniPod is an ideal platform for bi-hormonal designs, essentially providing the capability of a dual-chambered pump. Delivery of the two hormones is directed by independent algorithms. Glucagon is particularly important for its role as a safety net to prevent hypoglycemia. Keep in mind the goal of the AP is tight glycemic control with minimal glycemic variation. In both systems insulin and glucagon are delivered in micro boluses (pulses) based on glucose results and other inputs. There is no basal insulin delivery.

Another point of differentiation in these systems is whether the algorithm constantly changes or remains constant once set. Several systems apply what can be described as "artificial intelligence" to continually change the amounts of insulin, or insulin and glucagon, delivered based on various inputs. These inputs include glucose levels, food intake, exercise and more, because as we know, the reality is that insulin needs can vary tremendously day to day.

AP research teams are showing that there is no one-size-fits-all AP system. AP research and systems will develop and evolve over time. Insulet is committed and continues to work closely with AP research teams around the world to meet their needs and goals.

Through *CPT Corner* we'll keep you informed of this progress. We'll also share learnings from AP research about diabetes management that CPT trainers and pump users can put into action now. That's the focus of AP Part 2…so stay tuned.