Portable Bionic Pancreas

Wireless Blood Glucose Control

When researchers from Boston University and Massachusetts General Hospital teamed to make automated blood glucose control a reality, they engaged industry experts to create visionary technology for a closed-loop "bionic pancreas". Egret Technologies was asked to design and build prototypes of the bionic pancreas for FDA regulated outpatient research trials to include children and young adults. Using Egret Technologies' proven design expertise in wireless medical devices and ability to provide rapid turnaround, the researchers achieved a 30-day improvement to their FDA acceptance schedule with a portable, compact and power-saving design.

Situation: For millions of people with Type 1 diabetes (T1D) the challenge of monitoring and regulating blood glucose levels to prevent complications from the disease is a daily burden. A research initiative that holds promise for reducing that perpetual vigilance is the "bionic" artificial pancreas. A bionic pancreas aims to mimic the human endocrine system by continuously monitoring blood glucose levels, processing that data and introducing quantities of insulin and/or glucagon to the body. The goal of the bionic pancreas is to keep blood glucose levels within a normal healthy range. Results from in-hospital research of bionic pancreas technologies are promising and the potential for relief from manual monitoring looks closer. The next step in advancing the vision is taking the technology out of the hospital to every-day life.

Key factors in achieving out-patient success are:

- Small sized system that can be carried on the body without significantly impacting the patient's everyday life.
- Extended battery performance to maximize intervals between recharging.
- Reliable performance with robust data processing and fail-safe mechanisms to guarantee wellbeing.

With legacy knowledge from previous bionic pancreas trials, the requirement for FDA approval of an Investigational Device Exemption (IDE), and an aggressive schedule, the team needed an engineering services provider who had multiple skills. Egret Technologies was chosen as an expert in wireless medical device

development, with a team familiar with multiple-partner projects and knowledge of FDA regulatory requirements.

Solution: The collaborative project initiated by Boston University had major support from commercial diabetes care companies: Dexcom®, Tandem Diabetes® and SweetSpot®.

This innovative concept includes a small wearable unit containing a Dexcom G4 continuous glucose monitor (CGM) device and an Apple® iPhone® hosting the complex mathematical bionic pancreas algorithm. The device communicates wirelessly to the patient's Tandem Diabetes t:slim insulin and glucagon infusion pumps with commands to adjust doses based on the bionic pancreas algorithms.

Understanding the partners' goals, Egret Technologies went to work on four critical areas:

- Small Form Factor – By creating a sleek case that housed the iPhone, the Dexcom G4 Receiver, electronics for data security, battery and power management, a solution was developed that could be carried in a patient's pocket or purse.
- Single Daily Charge Power Management – By attentive power budgeting for the constituent components and design of the charging and power management circuit, the goal of a single charging event per day was achieved.
- Reliable Performance – Egret Technologies' developed hardware and firmware was integrated with components from the other partners and the complete system was rigorously tested to ensure the quality required for regulatory approval.
- Fast Turn – Originally slated to require more than four months, the project was completed in just ten weeks.

"Turning Innovation into Profit" Results:

In FDA-regulated clinical research world, the path to success is first measured by quality and speed.

Upon the FDA's approval of the IDE, Dr. Ed Damiano, Principal Investigator for the research team said, "Egret Technologies delivered a working prototype of our bionic pancreas ahead of schedule and exactly to spec. The Egret team was highly professional while remaining extremely flexible and responsive to our needs. After such a positive experience with Egret, we look forward to working with them again as we begin the product development phase of our project."

Egret Technologies is a superior electronic design partner to global vendors of technology products. We are an innovative, solution-driven, US-based engineering design firm specializing in wireless, optical, electronic, and mechanical hardware, as well as embedded software systems. We provide concept development, product design and project engineering. Contact Egret Technologies at (954) 518-9645 or Innovate@EgretTechnologies.com