



2015 was an Exciting Year for Dose Safety!

I want to share some of our company's great news, as we get closer to reaching our dream of being part of a commercially available automated insulin delivery system that helps people with diabetes live a more independent life.

NIH SBIR Grant.

We are now in the second year of our NIH SBIR grant. Our study will be conducted in two phases:

- 1) Five days in a hotel to assess the safety and efficacy of the Dose Safety Controller (DSC) among patients with Type 1 Diabetes (T1D) and its ability to prevent or decrease the risk of hypoglycemia. The system's ability to work under all circumstances and conditions will also be assessed.
- 2) Four to six weeks in an outpatient at home setting. We will assess the safety and efficacy of the DSC among patients with T1D and who are hypoglycemia unaware. We will examine the ability of the DSC to restore hypoglycemic awareness after 4 – 6 weeks. It is expected that the DSC will restore hypoglycemia awareness by reducing the participant's exposure to hypoglycemia. We will also examine psychological and cognitive variables that may be associated with the use of our system.

We expect to enroll from 20 to 30 subjects in the study. We are working with a continuous glucose monitor (CGM) and an insulin pump manufacturer to develop a new iPhone based artificial pancreas (AP) investigational device for use in our studies. This device will take full advantage of the insulin administration and safety features of our updated control algorithm.

Dose Safety Controller Update

The updated DSC serves to reduce the high cognitive load on people with diabetes through automated insulin administration during real life "in the wild" device operating conditions. The DSC has three principle capabilities:

- 1) Automated transitions between open loop, hybrid closed loop and fully automated closed loop (no premeal bolus) operating modes.
- 2) Basal insulin safety monitor when in open loop mode.
- 3) Device fault tolerance safety features.

Basically the controller is a hybrid closed loop algorithm with fully automated closed loop control as a safety backup. The fully automated control capability is designed to augment hybrid closed loop mode in various circumstances such as, missed pre-meal bolus, incorrect carbohydrate counting, variations in G-I motility, limited mental capacity, unanticipated exercise, etc. If the patient chooses to not manually bolus pre-meal then the fully automated closed loop capability will control blood glucose 24/7.

Software runtime performance optimizations

Since our controller will run in microcontroller chips commonly used in insulin pumps, our software must have minimal power consumption requirements. In November we successfully completed our first round of software optimization. We will complete the second rounds of optimization this month as part of our IDE submission for the hotel studies.

Advanced Technologies and Treatments for Diabetes (ATTD) conference.

We are pleased to present our E-poster: "Automated Insulin Delivery 'In The Wild'", which highlights the device fault tolerance safety features in our updated control algorithm. We will be making 2 presentations at the AP Data Club Forum on Saturday February 6th: "Ad lib living studies give way to Hybrid / Fully Automated Closed Loop Artificial Pancreas" and "Algorithmic Changes Reduce Compute Time by 46% for AP Controller Software".

If you are attending the ATTD Conference I will look forward to seeing you there.

Richard Mauseth, MD, CEO, Dose Safety Inc.