Efficacy and Computational Efficiency of the Dose Safety Hypoglycemia Prevention Module (HPM)

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Objective

Assess the performance and computational efficiency of the Dose Safety HPM.

The Dose Safety Controller (DSC) is an AP device control algorithm. The Fuzzy Logic Dosing Module (FLDM) provides automated closed loop control of blood glucose using insulin. The HPM provides an extra layer of patient safety; it augments the Low Glucose Suspend (LGS) dosing capability which is built into the design of the FLDM. **See Figure 1.**

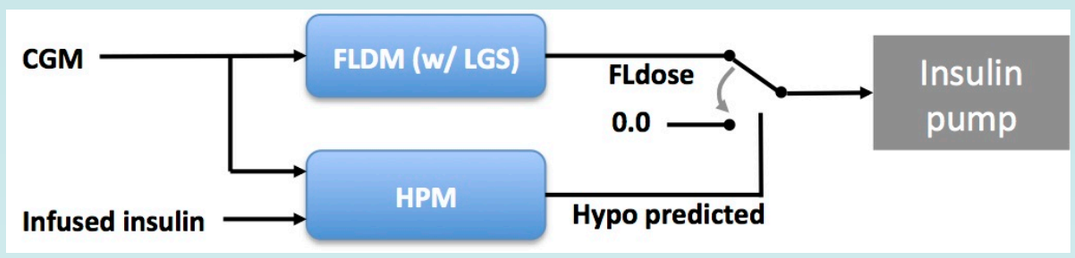

Figure 1

The HPM automatically suspends FDLM dosing when sensor glucose levels are predicted to approach a low limit. FDLM dosing resumes insulin delivery once sensor glucose levels recover.

Method

We generated the baseline statistical model using the procedure described in our 2014 ATTD poster. Glucose and insulin dosing data from ten 24-hr in silico test runs; using different subjects from those used to generate the baseline model, were processed by the HPM. Online learning continuously personalized the baseline model for each subject.

Because hypoglycemia events are least likely when glucose values are increasing, predictions and model updates were computed only when glucose was level or falling.

To increase the number of low-glucose events, we set the low threshold to 90 mg/dL. We believe that to be sound because glucose predictions are based solely on machine learning pattern matching of the glucose and Insulin On Board signals; not a mathematical differential equation representation of the human glucoregulatory system. **See figure 2.** For the test, we defined a low glucose event as 2 consecutive glucose values below 90 mg/dL.

Results

Of the 16 low glucose events in the test datasets, 15 were predicted. The mean prediction time before the events was 47 minutes (SD=30.7). Of the 6 false positive predictions, the mean actual glucose at the time was 98 mg/dL (SD=11.5). Note that false positives below 100 mg/dL are considered safe.

Restricting the prediction and learning computations to when glucose was level or falling (slope <= 0) resulted in a 39% reduction in computation time. **See Figure 3**.

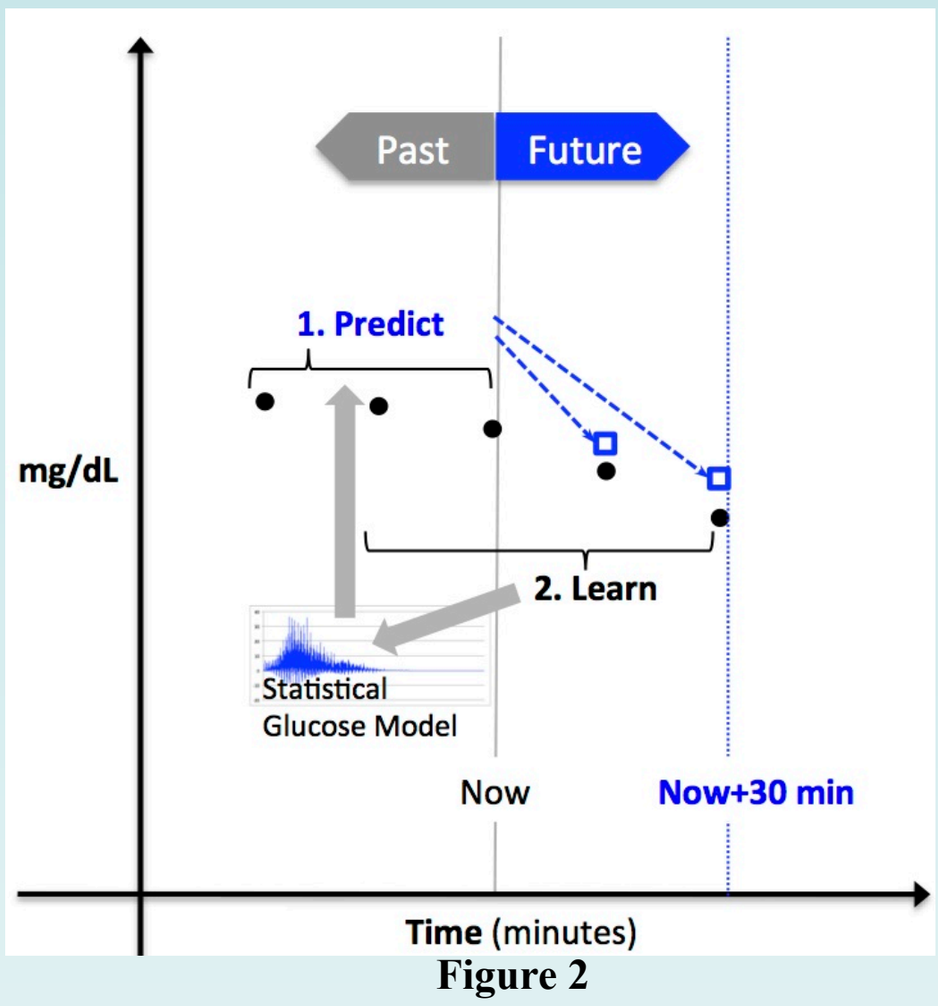

Figure 2

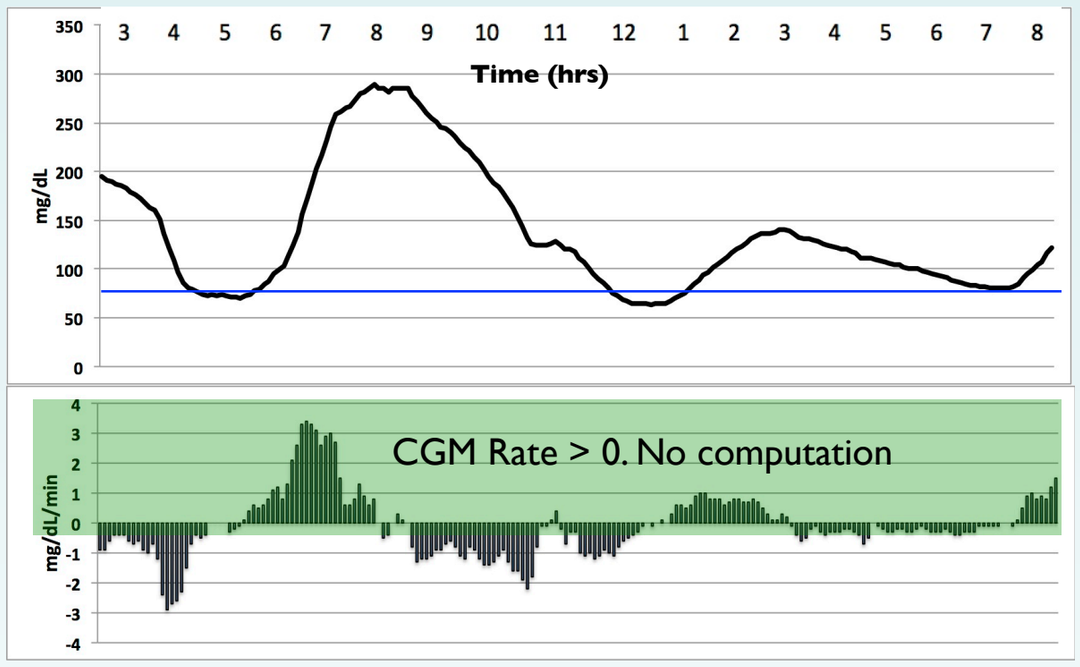

Figure 3

Conclusion

The Dose Safety HPM is safe and computationally efficient to use in an artificial pancreas device.

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