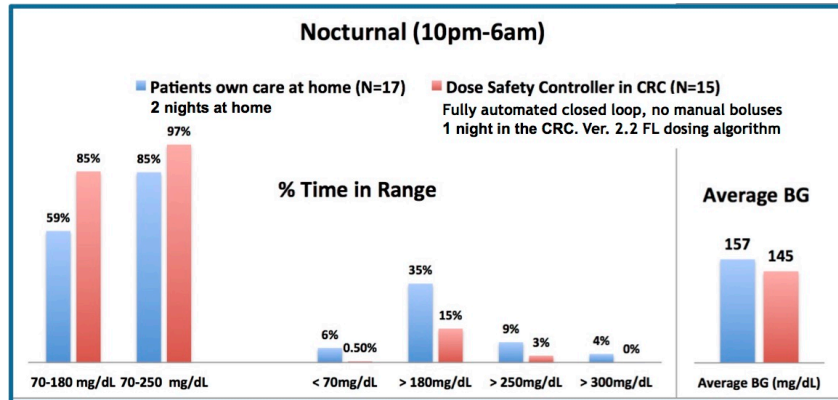
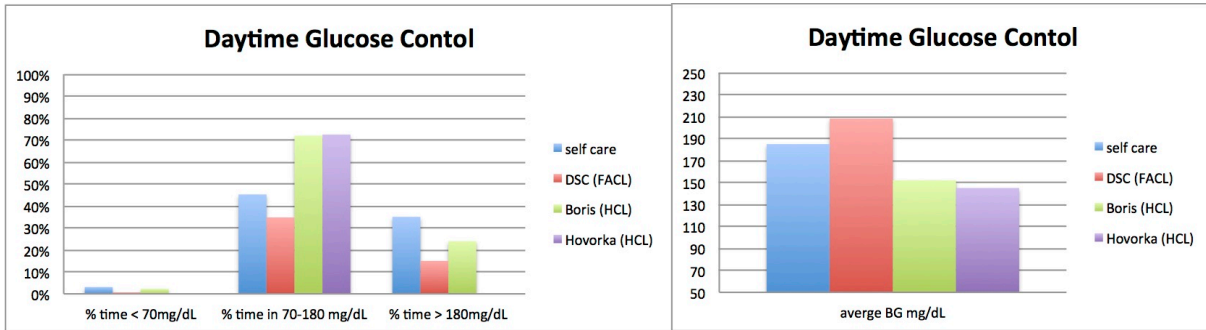


# Dose Safety Status Report – June 2016

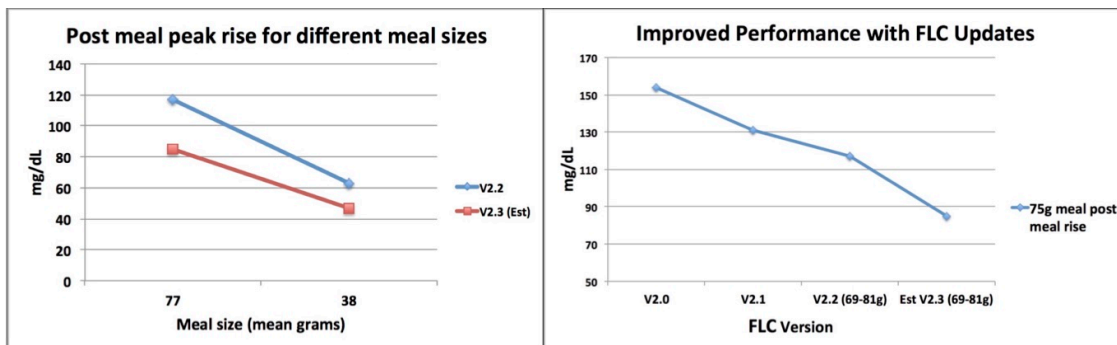
## 1) Nocturnal clinical data



## 2) Daytime clinical data



## 3) Suppression of postprandial rise using Fully Automated Closed Loop control



- Missed Boluses
- Poor carbohydrate counting/content
- Gastric emptying disorders
- Unexpected exercise
- Mentally challenged

## Dose Safety Status Report – June 2016

### 4) New investigational device in work for outpatient Hotel study



- Apple iPhone based, Dexcom G4 CGM, Insulet OmniPod
- Open Loop (manual), Hybrid CL and Fully Automated CL operating modes
- New version 2.3 FL dosing algorithm
- System fault tolerance for safe insulin delivery in daily living conditions
- Dexcom Share/Follow for remote monitoring

### 5) NIH-funded outpatient hotel study

- Objectives:
  - Validate Hybrid CL operating mode
  - Evaluate the 'glycemic cost' of the version 2.3 FL dosing algorithm in Fully Automated CL vs. Hybrid CL modes
- N=22
- Randomized crossover study
- 72-hr Hybrid CL and Fully automated CL arms