

Safe Automated Insulin Delivery During Daily Living Conditions

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Purpose



A dosing algorithm is Not Enough!

The objective of this research is to improve the safety of automated insulin delivery when encountering everyday system incidents such as: sensor changes/calibrations, system startup/shutdown, Continuous Glucose Monitor (CGM) and insulin pump communication errors, infusion set changes, insulin refills and battery changes.

Background

Our new system safety monitor (SSM) includes Boolean mode control logic, which allows hybrid or fully automated closed-loop insulin dosing only when the CGM and pump are operating normally. The system default operating mode is closed loop. The SSM suspends automated insulin delivery and transitions to the user's preprogrammed basal when it detects something is wrong. Automated closed loop insulin delivery resumes when problems are resolved.

Methods

Study ID	Interruption type	# interruptions
301V2, 304V1, 304V1, 302V3, 302V4, 303V2, 303V3, 304V1, 305V2, 305V4	CGM signal interruption	18
302V4, 303V3, 304V1, 305V2, 305V3	Pump communications interruption	20
301V1, 305V3	APS platform user error	2
TOTAL		40

Table 1

Forty (40) system incidents (Table 1), resulting in missed automated insulin doses, occurred in 17 Daily Living clinical studies in the CRC. In each case, because the SSM was not yet implemented, the on site engineer had to intervene and manually restore closed-loop dosing.



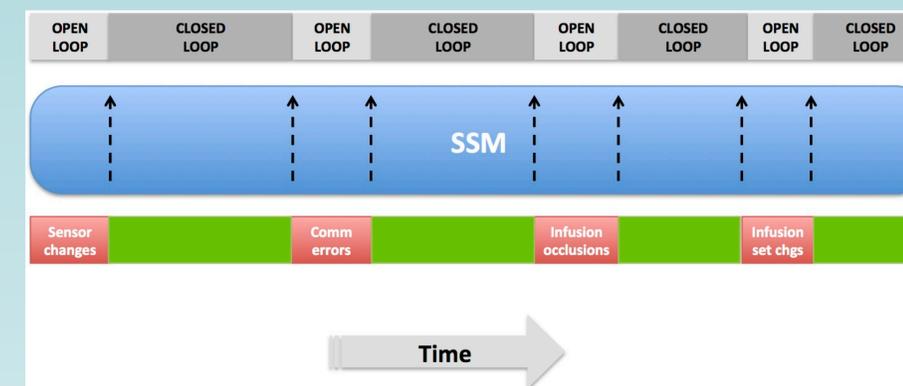
Figure 1

New software in the Dose Safety Controller monitors the status of the CGM and insulin pump in real-time, and automatically enables / disables closed loop operation accordingly. The SSM inputs & outputs are shown in figure 1. The values of Boolean variables CgmSysOpNormal and PumpSysOpNormal are calculated every 5 minutes.

CgmSysOpNormal is a function of the CGM system communications heartbeat, CGM system status bits and the CGM time stamp values.

PumpSysOpNormal is calculated based on the pump communications heartbeat, and pump system status bits.

Methods



In real-time the SSM detects non-normal conditions in the system components and automatically switches between manual open and closed loop insulin delivery.

Results

We analyzed the 40 system incidents given the SSM mode logic and concluded that 38 (95%) of the incidents would have been detected and closed loop dosing temporarily suspended.

The remaining 2 incidents were caused by operator error and not detectable by the SSM.

Conclusions

The retrospective analysis of system incidents in prior clinical studies showed that the SSM would have successfully detected 95% of the system faults and temporarily suspended closed loop dosing. This analysis shows that our fuzzy logic dosing algorithm in conjunction with the SSM, will safely administer automated insulin delivery during daily living conditions.

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