

Hypoglycemia Avoidance After Adoption of a Next-Gen CGM System Including a Predictive Low Glucose Alert

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Background

- Randomized controlled trials that examined the efficacy of real-time continuous glucose monitoring (rtCGM) use enabled device alerts and alarms and reported less than 15 minutes per day spent in hypoglycemia at study end.^{1,2} The IMPACT study examined the efficacy of intermittently scanned CGM (isCGM) use – absent alerts and alarms – and reported 48 minutes daily in hypoglycemia at study end,³ suggesting low threshold alerts are important components of rtCGM systems.
- Consensus statements have recommended that low threshold alerts be set at 70 mg/dL.⁴ However, a higher threshold alert setting of 80 mg/dL can provide additional time for interventions prior to the onset of clinical hypoglycemia.⁵
- When glucose levels are rapidly falling, users may still reach a cognitive impairment threshold even if they receive a threshold alert.
- Advanced warning of impending hypoglycemia, such as the Urgent Low Soon alert introduced in Dexcom G6, may reduce the time spent at very low glucose levels.

1. Beck, R.W. et al., JAMA, 2017. 317(4): 371-378.
2. Heinemann, L. et al., Lancet, 2018. 391(10128): 1367-1377.
3. Bolinder, J. et al., Lancet, 2016. 388(10057): 2254-2263.
4. ADA Workgroup on Hypoglycemia, Diabetes Care, 2005. 28(5): 1245-1249.
5. Davey, R.J. et al., JDST, 2010. 4(6): 1457-1464.

Methods

- Retrospective evaluation of device use and glycemic control
- Approximately 1,400 anonymized users
Transitioned from G5 to G6 devices
≥30 days of CGM data before & after transition
- Data collected from May-August 2018
- Required Urgent Low Soon (ULS) alert enabled (new in G6, default setting)
- Bin patients according to Low Threshold Alert setting (70 or 80 mg/dL)

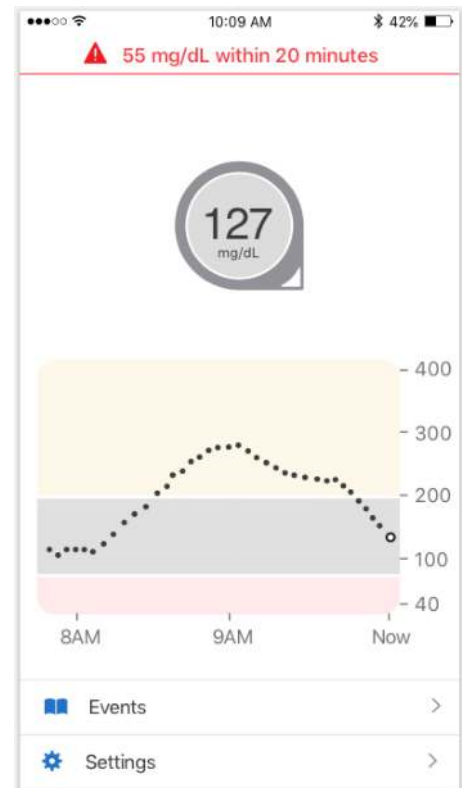


Figure 1

The ULS Alert (G6 only) is triggered when an estimated glucose value ≤55 mg/dL is predicted within the next 20 minutes.

Results

- The ULS alert remained enabled among >97% of G6 users.

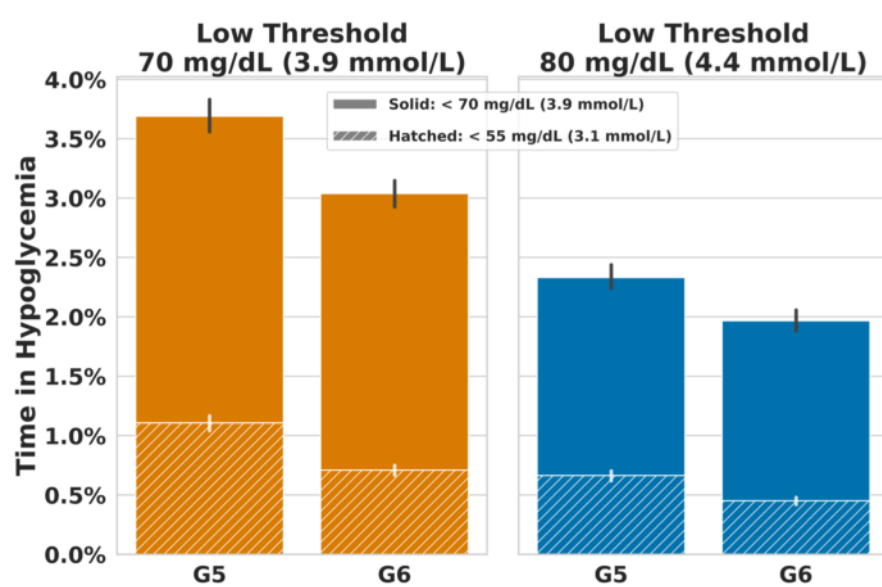


Figure 2: Time in Hypoglycemia

The transition to G6 was associated with significantly reduced biochemical (<70 mg/dL) and clinical (<55 mg/dL) hypoglycemia, independent of low threshold alert setting ($p < 0.01$).

Figure 3: ULS Activations

Having the low threshold alert at 70 mg/dL was associated with significantly more ULS activations ($p < 0.001$).

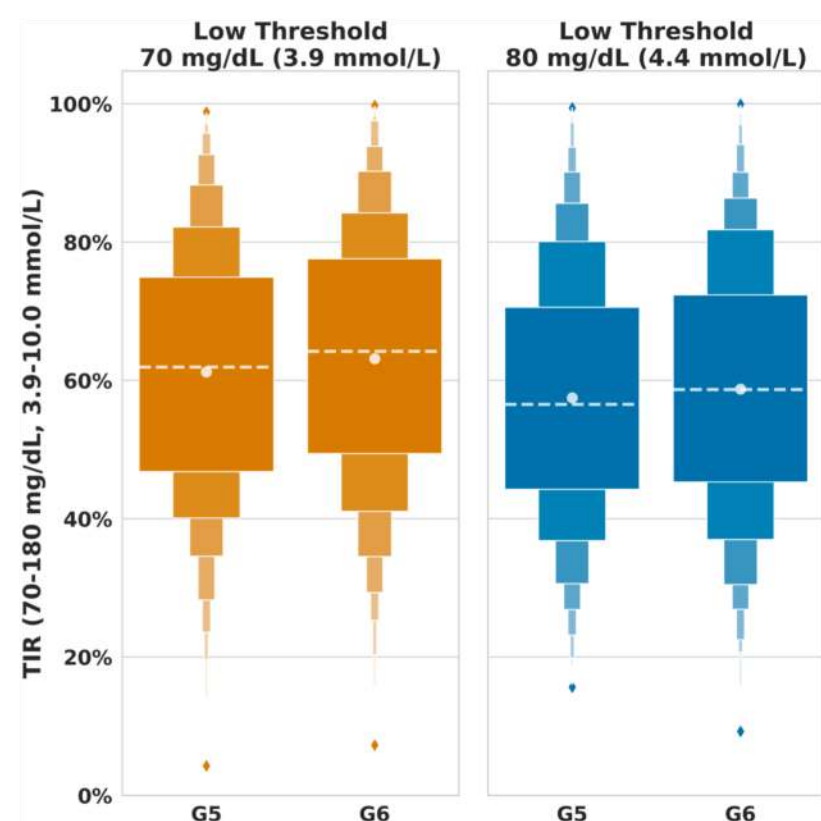
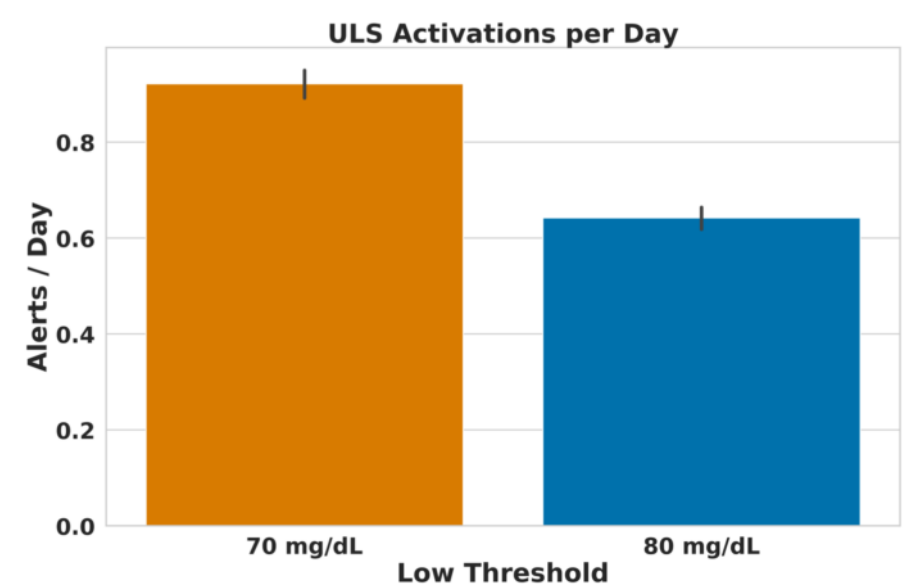
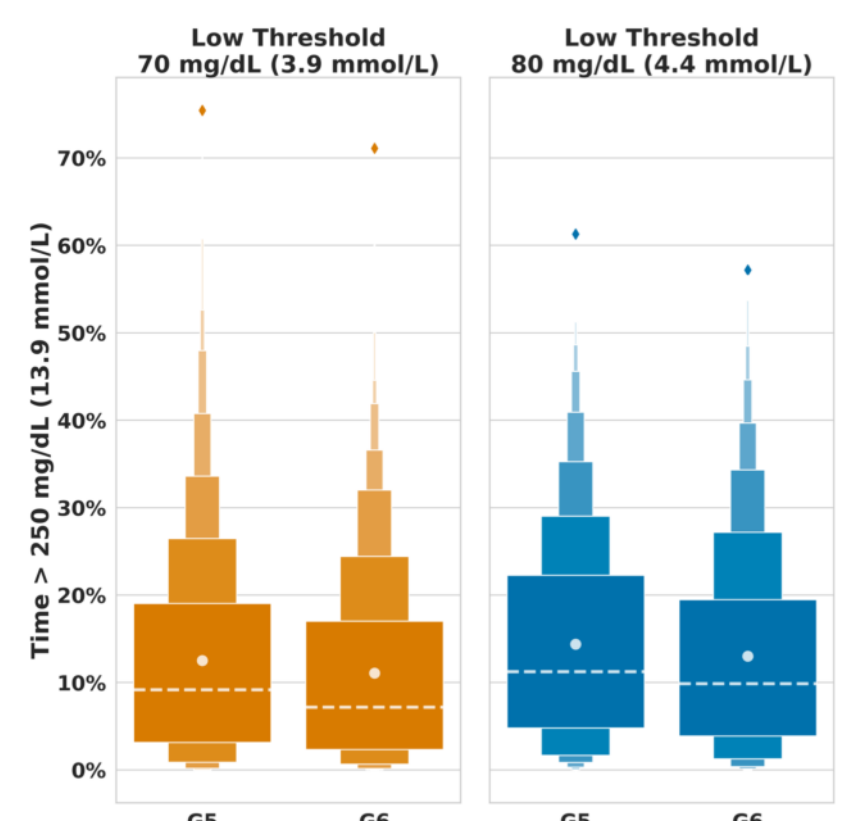


Figure 4: Time in Range

G6 use was associated with more TIR, with a significant difference for those with a low threshold alert of 70 mg/dL ($p=0.05$).

Figure 5: Time in Hyperglycemia

Time spent > 250 mg/dL fell significantly after the transition to G6 for users of both low threshold alert settings ($p=0.02$).



Letter value plots displaying upper and lower quantile boundaries (fourths, eighths, etc.), with outliers represented as diamonds. The largest, central box represents the IQR. The dashed line and dot represent the median and mean of the distribution, respectively.

Conclusion

- The incorporation of a predictive low glucose alert into G6 significantly reduces hypoglycemia relative to a CGM system without the predictive alert, independent of threshold alert setting.
- Findings suggest that reduced hypoglycemia did not come at the expense of increased severe hyperglycemia.
- Patients with a lower low alert threshold spent more time in hypoglycemia but less time in hyperglycemia.
- Correlational real-world data on over 1400 patients suggests that even experienced G5 users who transitioned to G6 with ULS saw a reduction in time spent in hypoglycemia.