

# AVOIDANCE OF GLUCOSE EXCURSIONS BY THE GUARDIAN CONNECT™ CGM SYSTEM- REAL-WORLD DATA

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## Introduction

The Guardian Connect™ continuous glucose monitoring (CGM) system allows users to view sensor glucose (SG) data on a smartphone. The system includes predictive glucose alerts that can be set to notify users between 10-60 minutes before a low or high glucose excursion occurs, with a default setting of 15 min before high, and 20 min before low.



The rates and durations of high and low glucose excursions following predictive alerts were evaluated. These results were compared to a control dataset when alerts were disabled.

## Methods

**Time period of CareLink™ data set evaluation:** Jan 2, 2017 to Jan 2, 2018

**Patient cohort:** 3,720 patients

**Inclusion criteria:** >5 days of SG data in CareLink™ database

### Analyses:

- Excursions were identified when SG values were beyond each user's pre-set high and low SG thresholds for ≥15 min.
- High and low excursions were analyzed in separate cohorts. Cohorts were further divided based on whether the user enabled predictive alerts at the time of the excursion.
- During times when no alerts were enabled, control timestamps were marked when a predictive alert would have been triggered.
- Excursion durations following the alert times were segmented into avoided, ≤20min, 20-60 min, and >60min.

## Results

Real-World User Settings	High	Low
SG Limit, mg/dL (mmol/L)	210 [170-250] (11.7 [9.4-13.9])	70 [65-75] (3.9 [3.6-4.2])
Time Before Excursion (min)	15 [7.5-15]	17.5 [10-20]

**Customizable Settings:** The table above shows the median and 25<sup>th</sup>-75<sup>th</sup> percentile of settings by users of the predictive alerts for both the high and low SG limits and the time before excursion (minutes).

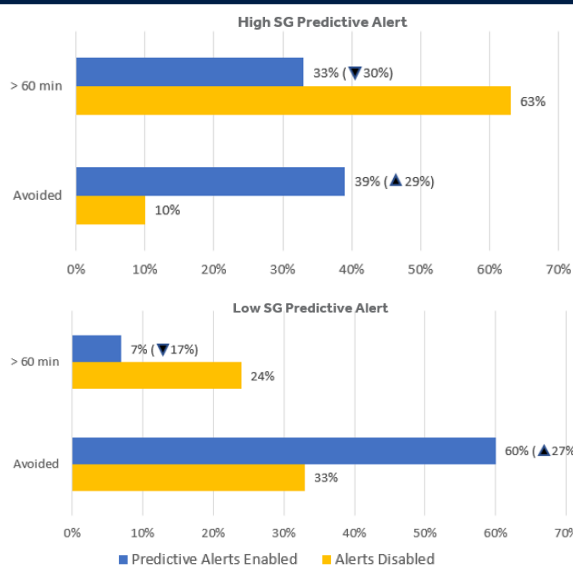
	Cohort	High SG Excursion		Low SG Excursion	
		Predictive Alerts Enabled	Alerts Not Enabled	Predictive Alerts Enabled	Alerts Not Enabled
Avoided	Total Alert Count	258974	296928	484900	40827
	Excursion Count	100187	29123	289306	13542
	% of Total Alerts	39%	10%	60%	33%
≤20 min	Excursion Count	28626	30404	79613	8883
	% of Total Alerts	11%	10%	16%	22%
	Excursion Count	44130	49437	82203	8578
20-60 min	% of Total Alerts	17%	17%	17%	21%
	Excursion Count	86031	187964	33778	9824
	% of Total Alerts	33%	63%	7%	24%

**Excursion Avoidance Following Predictive Alerts:** Percentages of each alert resulting in an excursion and compared to control during periods of disablement, are shown. Fisher's Exact test was used to evaluate the odds of avoiding an excursion with predictive alerts enabled [Low = 2.98 95% CI 2.92 - 3.04; p<0.001] [High = 5.80 95%CI 5.72 - 5.88; p<0.001].

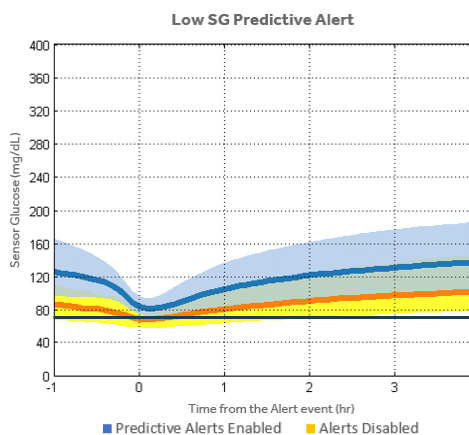
## Results

Median Duration [25 <sup>th</sup> -75 <sup>th</sup> percentile]	Alerts Enabled	Alerts Disabled
High Predictive, min	20 [0-95]	105 [30-265]
Low Predictive, min	0 [0-20]	15 [0-60]

**Excursion Duration Following Predictive Alerts:** A rank sum test showed significant (p<0.001) differences in the distribution of excursion durations for both high and low predictive alerts when alerts were enabled versus disabled



**Difference in Excursion Occurrence and Duration Following Predictive Alerts, Compared to Control:** The percentage point improvement for excursions avoided was 29% and 27% following predicted high and low alerts versus control. The percentage point reduction for excursions >60 minutes was 30% and 17%.



**Glucose Traces Surrounding Low Predictive Alerts Compared to Control:** The median and quartile ranges of the sensor glucose traces 1 hour preceding to 4 hours following an actual low predictive alert (blue) compared to control (yellow), during times when the predictive alerts were disabled. The visualization was run on 112,264 and 14,164 randomly sampled traces per periods of alerts being enabled and disabled, respectively. The longer rise time and greater time below range (70 mg/dL [3.9 mmol/L], horizontal line) can be seen in the control compared to the enabled post-alert period.

## Conclusions

Predictive alerts, like those of the Guardian™ Connect system, are useful for tracking glucose levels and enabling timely actions that help patients avoid high and low glucose excursions. The odds of avoiding excursions were found to be 3 times greater with low predictive alerts enabled and 6 times greater with high predictive alerts enabled, versus when alerts are not enabled.