

Performance of the Predictive Low Glucose Management Feature of the MiniMed 640G System in a User Evaluation Study

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Background & Methods

MiniMed 640G system and second-generation Enlite sensors are not approved in the US.

Figure 1. MiniMed 640G System



The MiniMed 640G system includes the SmartGuard™ feature and the next generation Enlite sensor. This system allows for the automatic suspension of insulin delivery using a predictive low glucose management algorithm, referred to as *suspend before low*. Suspend before low is triggered when it is predicted that the pre-set low glucose limit will be reached within 30 minutes.

Insulin delivery is automatically resumed after a minimum of 30 minutes and a maximum of 2 hours, and when it is predicted that the sensor glucose (SG) value will be above the pre-set low glucose limit.

Suspend before low and automatic resumption of insulin delivery can be programmed to occur with or without alerting the user. If the user-set low limit is reached, an alert that escalates will be triggered. Settings for the suspend at low, suspend before low, and programmable alerts can be customized with up to 8 time periods over the 24-hour clock.

Study Methods

Subjects with type 1 diabetes were enrolled at 3 European centers and provided with MiniMed 640G systems for 4 weeks. Questionnaires were completed at baseline and at the end of the study. Pump and sensor data were uploaded at the end of the study for analysis.

Figure 2. Study Protocol

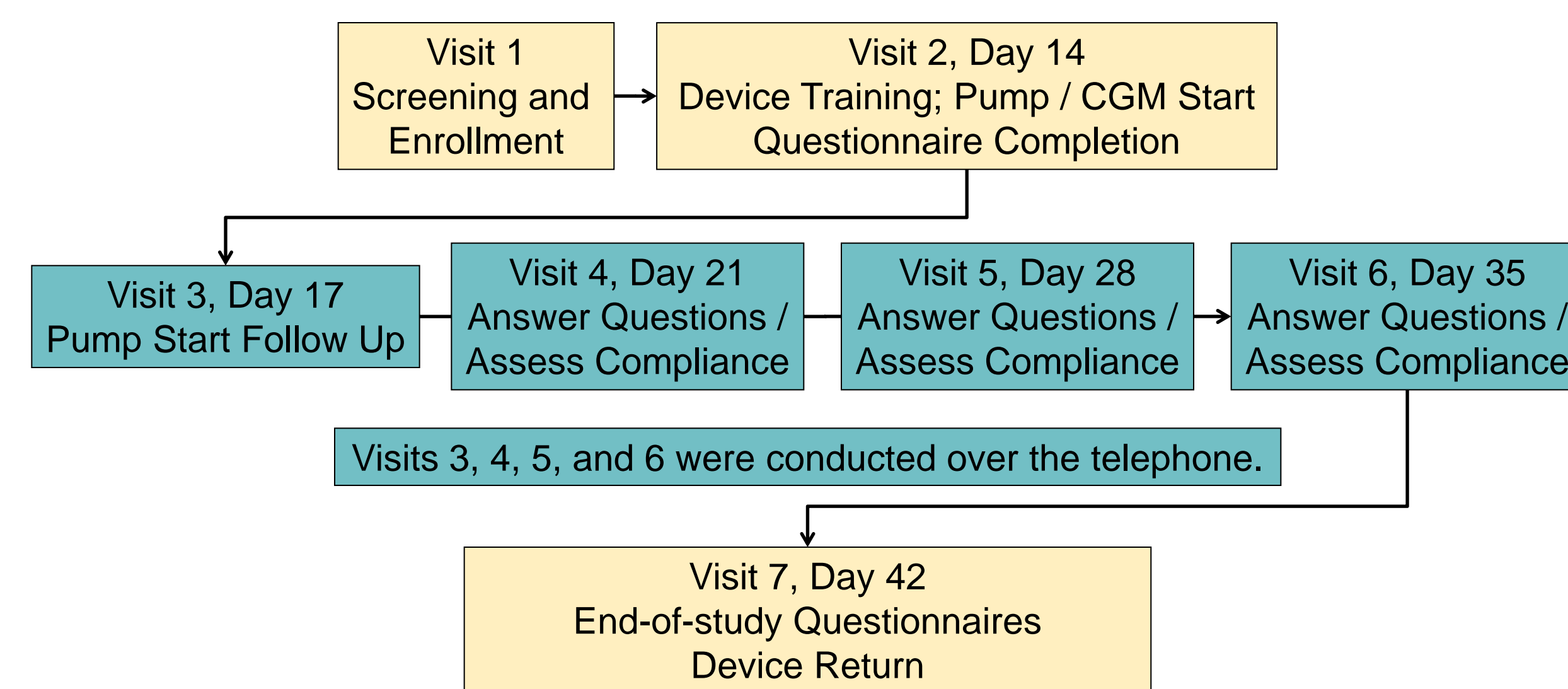


Table 1. Baseline Characteristics

	All (N=40)	Adult (n=24, ages 19-65)	Pediatric (n=16, ages 9-17)
Age (years)	31.7 ± 17.7	43.8 ± 12.0	13.4 ± 2.5
Male (N, %)	22 (55.0%)	13 (54.2%)	9 (56.3%)
Body Mass Index (kg/m ²)	23.5 ± 4.0	25.2 ± 3.5	21.0 ± 3.4
Diabetes duration (years)	17.2 ± 13.3	23.6 ± 13.3	7.4 ± 4.4
Baseline A1C (%)	7.6 ± 0.9	7.7 ± 0.7	7.4 ± 1.1

Continuous variables are given as mean ± SD

Results

Characterization of Pump Suspension Events

- There were 2402 evaluable pump suspension events, 2.1 per subject-day
- Most (1645/2402=68.5%) occurred in the daytime hours of 8:00 AM to 10:00 PM and 31.5% occurred at night
- The overall mean (±SD) duration of an automatic pump suspension event was 56.3±9.5 min (median, 58.0 [IQR, 49.2-64.2] min)
- The mean SG nadir following pump suspensions was 70.3±7.1 mg/dL (median, 70.8 [IQR, 67.3-75.0] mg/dL)
- Of the 2402 suspend events, 2322 were suspend before low events and 80 were suspend on low events
- In 83.1% of the suspend before low events where the pump stopped delivering insulin, the SG value never reached the pre-set low limit
- The overall mean SG value was 163.6±16.9 mg/dL (166.9±17.20 mg/dL daytime, 159.6±19.6 mg/dL nighttime)
- Suspend events occurred throughout the day and night. For all suspensions, there was a peak in the early afternoon, while for those lasting the maximum of 2 hours, the peak was at night

Figure 3. Daytime Events: Duration and Type of Restart

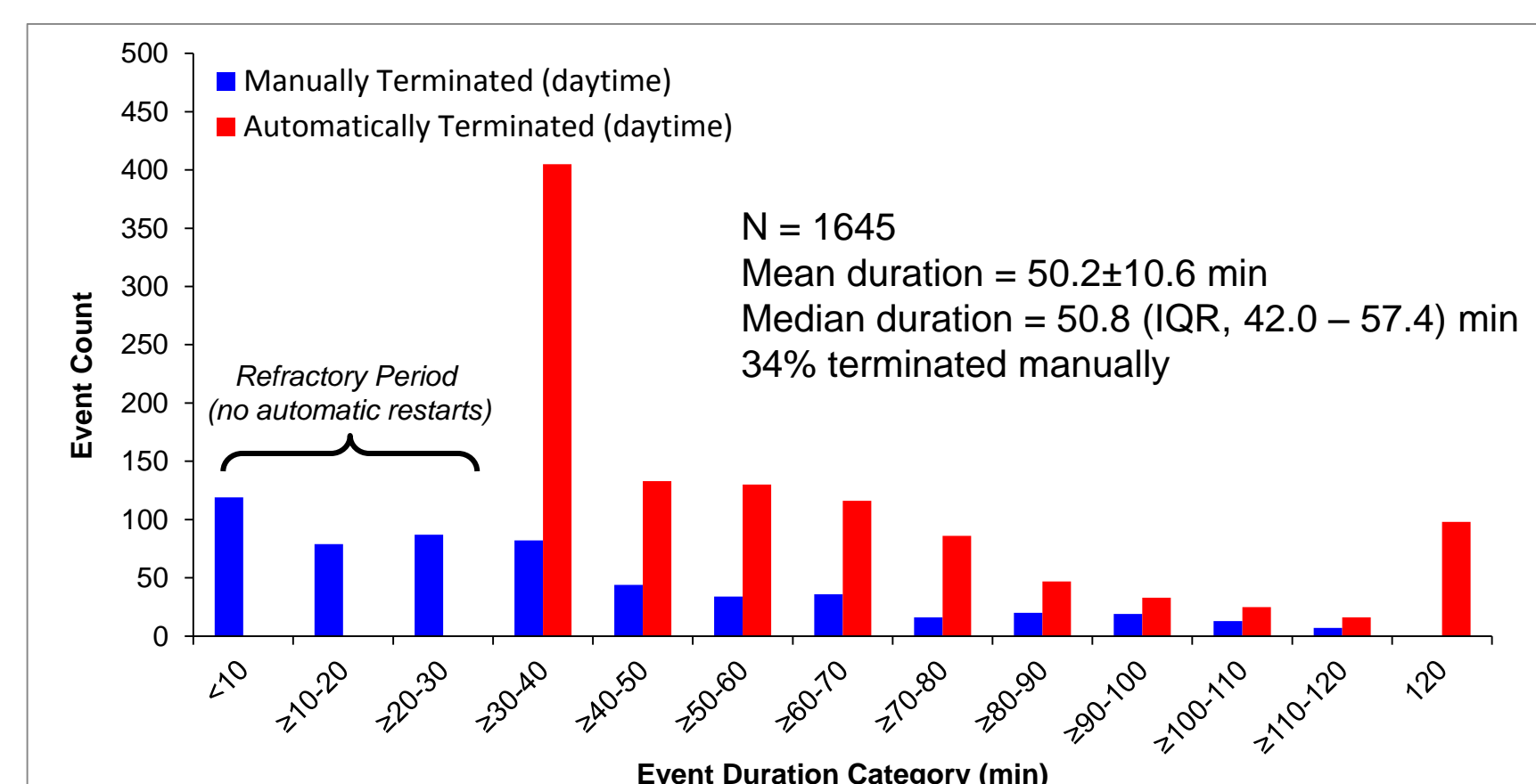


Figure 4. Nighttime Events: Duration and Type of Restart

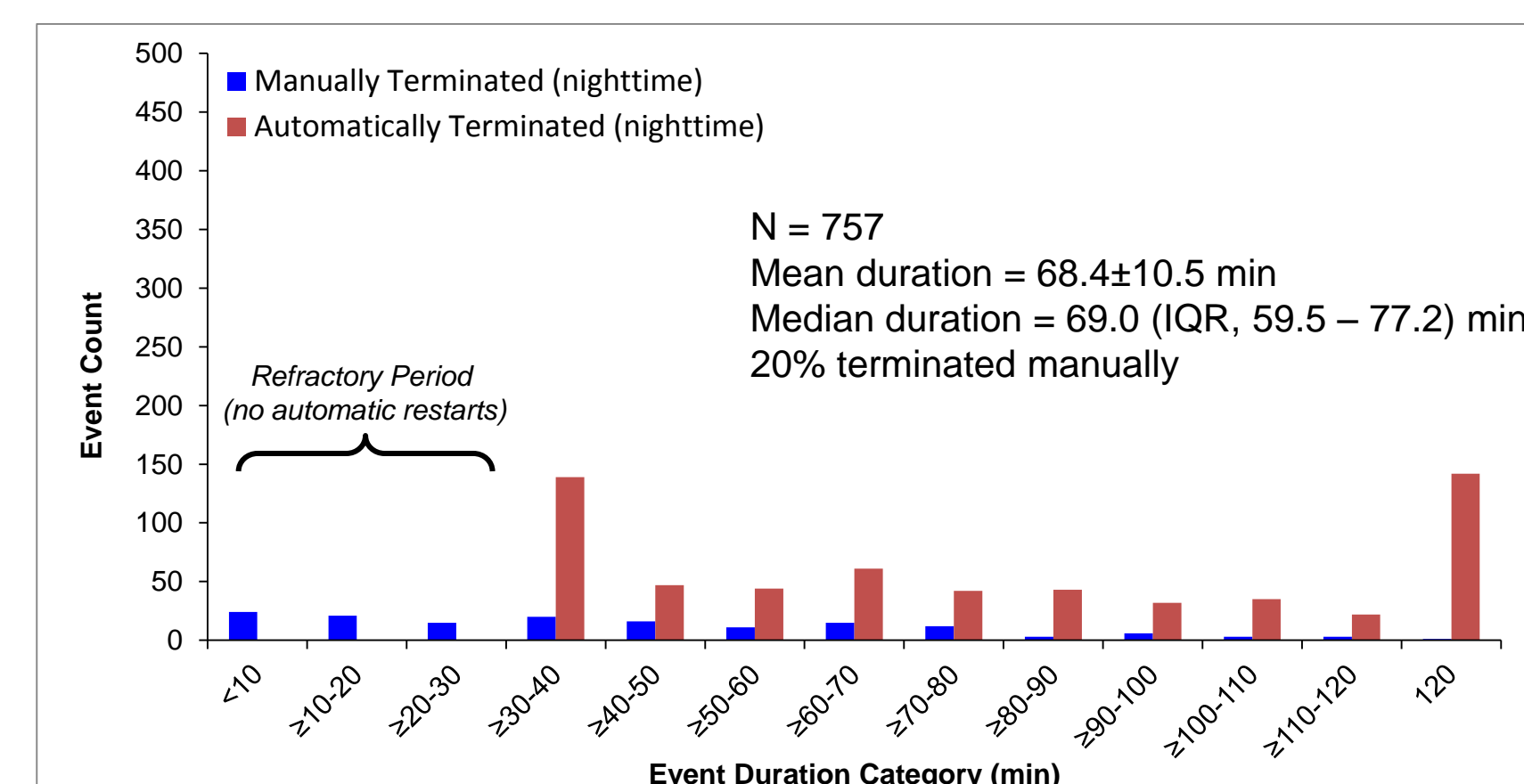


Figure 5. SG Trajectories of 2-Hour Events

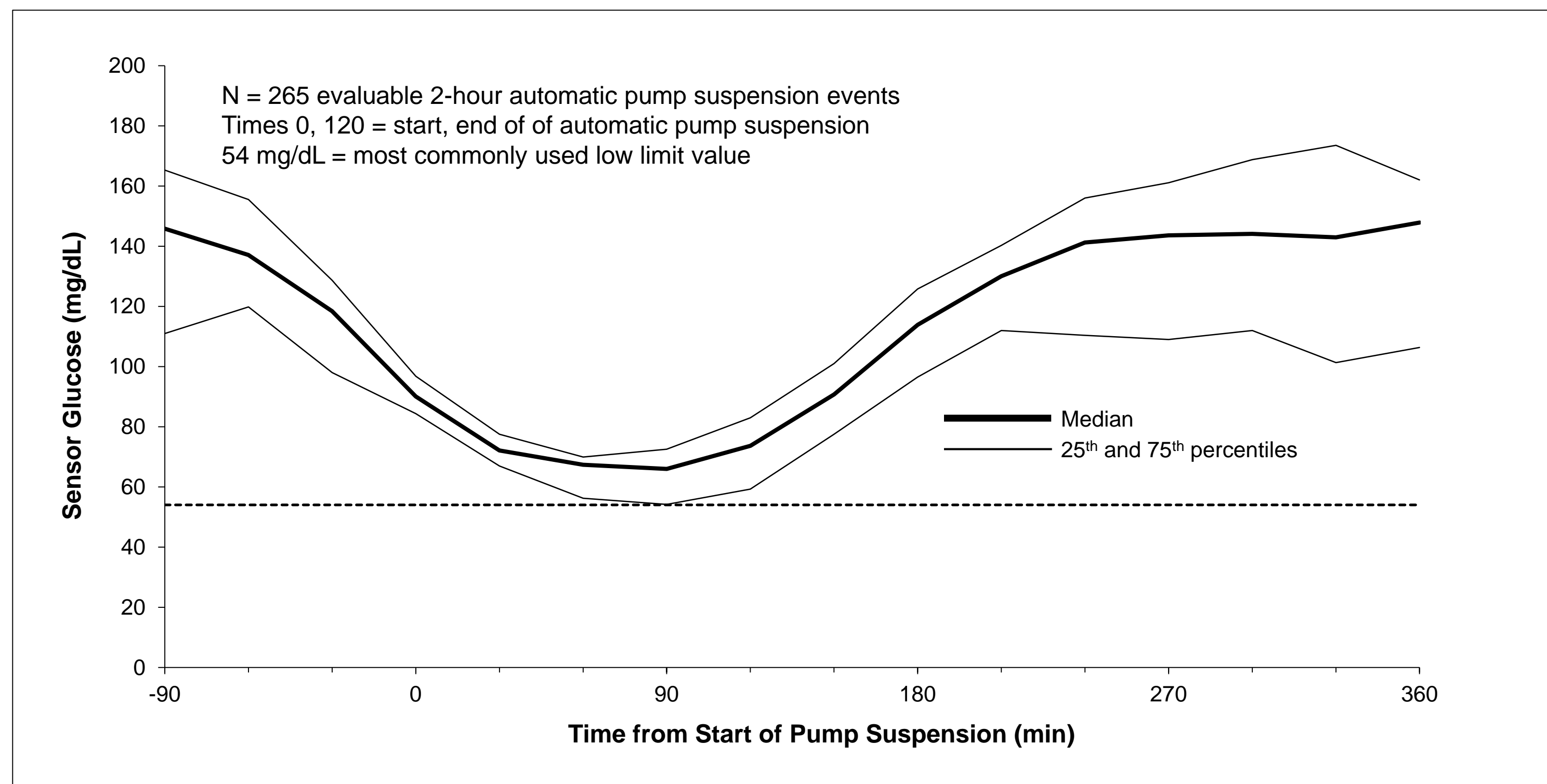


Table 2. Selected End-of-Study Questionnaire Responses

Question	Adult		Pediatric	
	Median	Min, Max	Median	Min, Max
The SmartGuard features are easy to use	6	5, 7	6	4, 7
The SmartGuard features make it easier for me to manage my lows	6	4, 7	6	5, 7
MiniMed 640G helps me achieve better glucose control	6	4, 7	7	3, 7
MiniMed 640G is easy to use and reduces some of the burden of my daily diabetes management	6	4, 7	6	4, 7
I would like to continue using MiniMed 640G	7	4, 7	7	4, 7

Allowable answers ranged from 1 ("strong disagreement") to 7 ("strong agreement").

Figure 6. Hypoglycemia Prevention

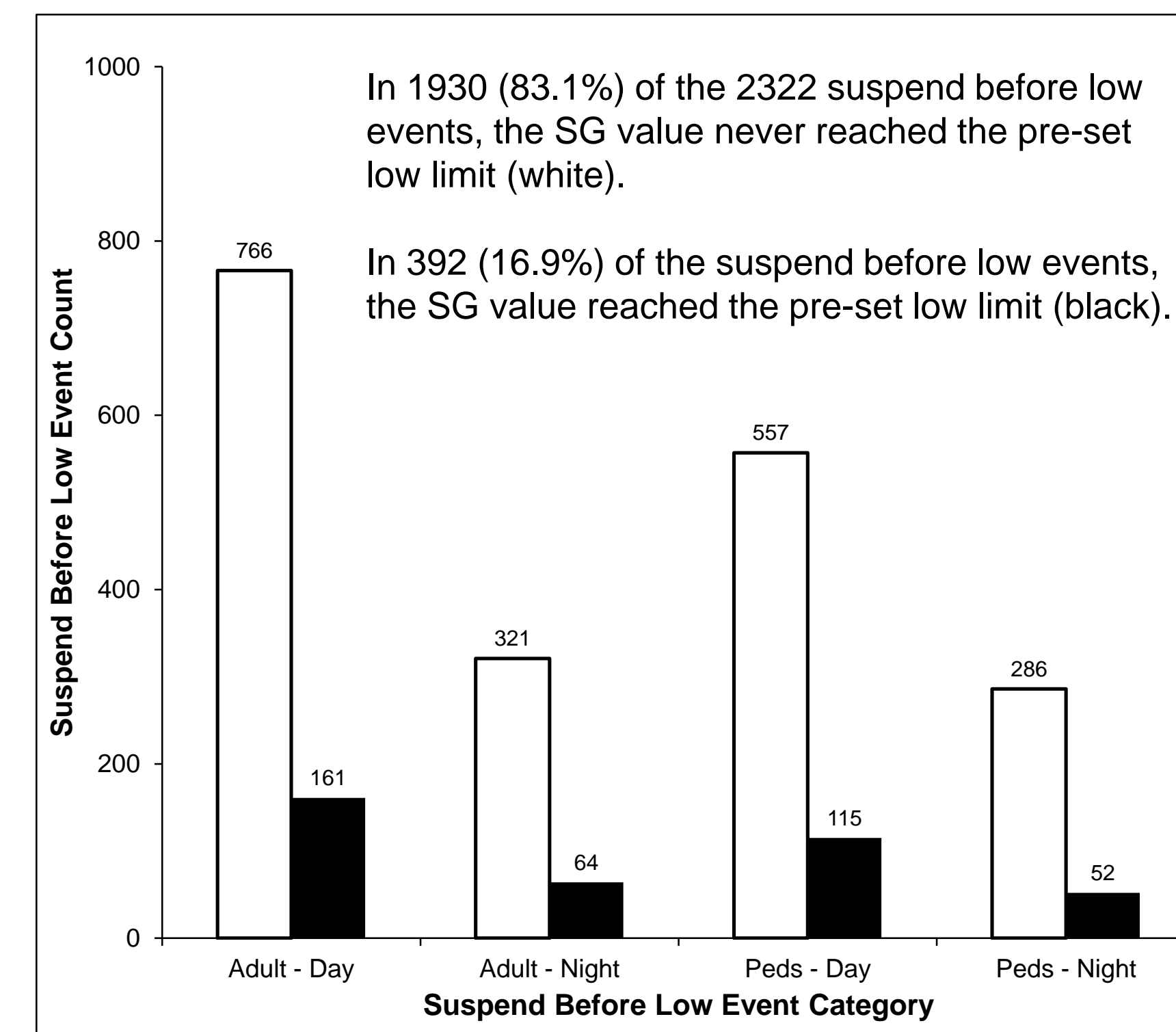


Table 3. Sensor and BG Values

	N	Mean ± SD (mg/dL)
Sensor Glucose: Pre-Study	18	158.9 ± 17.1
Sensor Glucose: Study	18	162.1 ± 20.9
Blood Glucose: Pre-Study	38	176.9 ± 32.5
Blood Glucose: Study	38	175.2 ± 25.9

N, number of subjects in each phase with both pre-study and study phase values for comparison. Only 18 subjects had pre-study SG data available and 38 had pre-study SMBG values available.

Table 4. Sensor Accuracy

Absolute Relative Difference (ARD) between SG and SMBG Values	
SMBG per subject-day	5.8
Paired SMBG / SG Values*	2662
Mean ARD ± Standard Deviation	10.9 ± 13.8%
Median ARD	6.2%

*SMBG values did not include those used to calibrate the sensor.

Adverse Events

All adverse events were mild and resolved without sequelae except for one that was ongoing at the time of study completion. There was 1 urinary tract infection, 1 eczema under the sensor adhesive, 1 allergic reaction to sensor overtape, and 1 common cold.

Summary

- The MiniMed 640G system represents an advancement in technology utilizing a predictive suspend algorithm, automatic resumption of insulin delivery, customizable alerts and suspend limits up to 8 times per day, and on a new pump platform with a next generation Enlite sensor
- Automatic pump suspensions occurred throughout the 24-hour time period, at a mean rate of 2.1 per subject-day
- Nighttime pump suspension events tended to last longer than daytime events and were more likely to be terminated automatically
- These data suggest that the automatic suspension of insulin delivery with a predictive algorithm can help avoid sensor glucose reaching the programmed low limit, without significantly increasing hyperglycemia.

- Subjects found the MiniMed 640G system and its automated features easy to use, and felt it helped facilitate diabetes management

- The MiniMed 640G system represents a further advancement in automation and continues to lay the groundwork for closed-loop technology