

## SUPPLEMENTARY DATA

### Supplementary Table S1. Eligibility and Exclusion Criteria

#### Eligibility Criteria

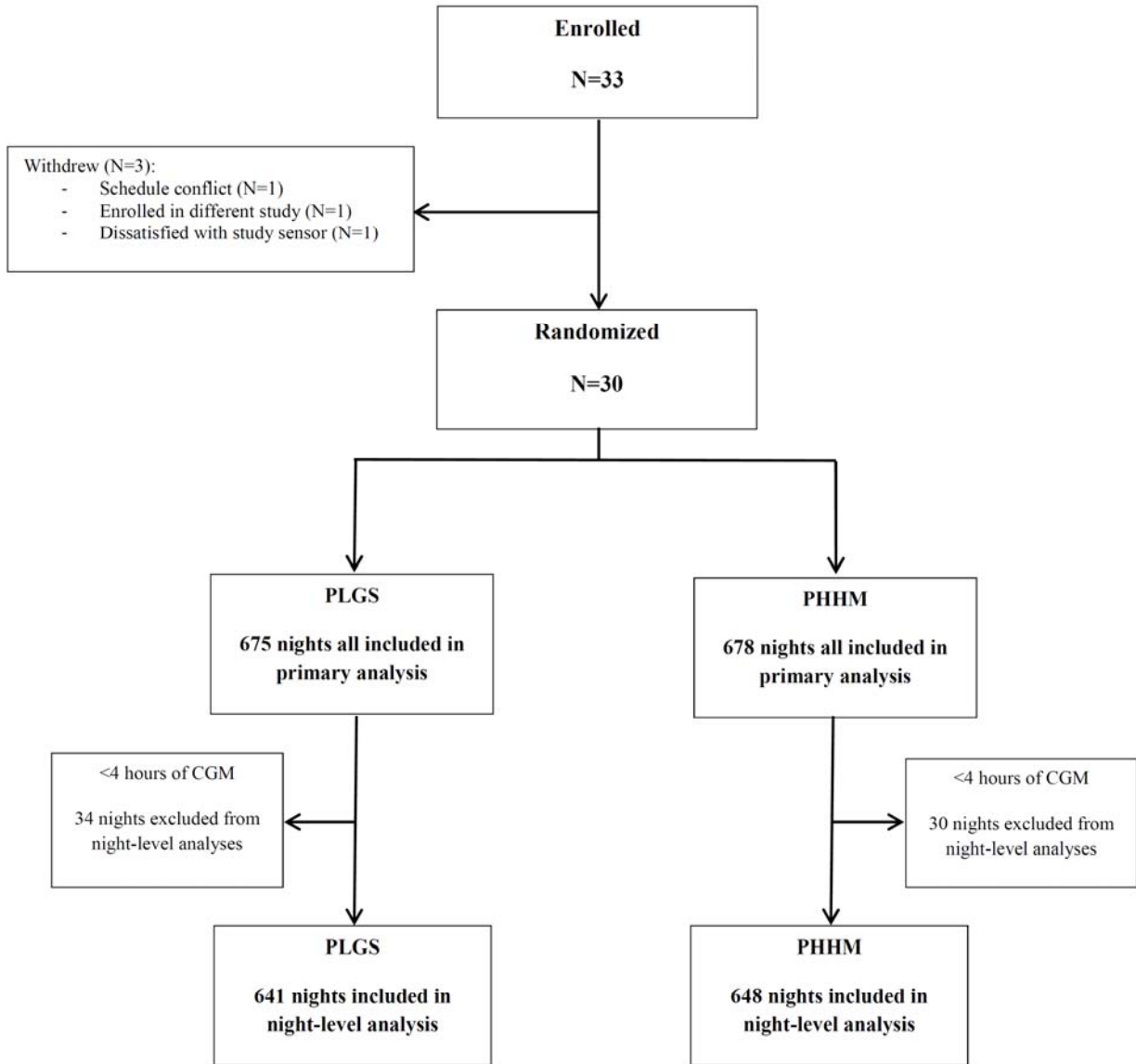
- 1) Clinical diagnosis of type 1 diabetes and using daily insulin therapy for at least one year and an insulin infusion pump for at least 6 months (*The diagnosis of type 1 diabetes is based on the investigator's judgment; C peptide level and antibody determinations were not required*)
- 2) Age 15 - 45 years
- 3) Glycated hemoglobin level  $\leq 10.0\%$  (86 mmol/mol)
  - Measured with DCA2000 or equivalent device for assessing eligibility
  - Glycated hemoglobin measurements performed as part of usual clinical care within 2 weeks prior to obtaining informed consent for participation in the trial may be used.
- 4) Uninterrupted internet access while study system in use overnight and for uploading of study data the following morning
- 5) Living with a significant other or family member (“companion”) committed to participating in all study activities, and being present and available to provide assistance when the system is in use at night
- 6) An understanding of and willingness to follow the protocol and sign the informed consent

#### Exclusion Criteria

- 1) Diabetic ketoacidosis in the past 6 months
- 2) Hypoglycemic seizure or loss of consciousness in the past 6 months
- 3) History of seizure disorder (except for hypoglycemic seizure)
- 4) History of any heart disease including coronary artery disease, heart failure, or arrhythmias
- 5) Cystic fibrosis
- 6) Current use of oral/inhaled glucocorticoids, beta-blockers or other medications, which in the judgment of the investigator would be a contraindication to participation in the study.
- 7) History of ongoing renal disease (other than microalbuminuria). Creatinine level to have been obtained within the last year if participant has diabetes of >10 years duration. If creatinine is >1.5 mg/dL (132  $\mu\text{mol/L}$ ), the participant is excluded.
- 8) Medical or psychiatric condition that in the judgment of the investigator might interfere with the completion of the protocol such as:
  - Inpatient psychiatric treatment in the past 6 months
  - Uncontrolled adrenal disorder
  - Abuse of alcohol
- 9) Pregnancy  
*If female and sexually active, must agree to use a form of contraception to prevent pregnancy while a participant in the study. A negative serum pregnancy test will be required for all premenopausal women who are not surgically sterile. Participants who become pregnant will be discontinued from the study.*
- 10) Liver disease as defined by an ALT greater than 3 times the upper limit of normal

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Supplementary Figure S2. Study Flowchart



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**Supplementary Table S3. Participant Characteristics at Enrollment (N=30 Participants) – medians (IQR) or n (%)**

Characteristic	
Age (yrs)	31 (22, 38)
<i>Range</i>	15 to 43
Male	15 (50%)
Race	
White non-Hispanic	26 (87%)
Hispanic	2 (7%)
Pacific Islander	1 (3%)
Unknown	1 (3%)
Diabetes duration (yr)	17 (11, 27)
<i>Range</i>	3 to 38
Body-mass index (kg/m <sup>2</sup> )	26.4 (23.0, 30.1)
Daily insulin dose (U/kg/day)	0.58 (0.46, 0.68)
Enrollment HbA1c (%)	7.5 (6.9, 7.7)
(mmol/mol)	58 (52, 61)
Randomization HbA1c (%)	7.1 (6.7, 7.4)
(mmol/mol)	54 (50, 57)
End of study HbA1c (%)	7.1 (6.6, 7.4)
(mmol/mol)	54 (49, 57)

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**Supplementary Table S4. Night-Level Secondary Insulin Outcomes**

	<b>PLGS</b>	<b>PHHM</b>	<b>P-value</b>
	<b>Nights</b>	<b>Nights</b>	
# Randomized Nights with Complete Insulin Data	640*	648	
Total Basal Insulin Units [median (IQR)]	7.0 (4.8, 10.0)	7.2 (5.3, 9.8)	0.37
Nights with Automatic Boluses [n(%)]	NA	506 (78%)	NA
Total Automatic Boluses Insulin Units <sup>†</sup> [median (IQR)]	NA	1.2 (0.4, 2.5)	NA
Number of Automatic Boluses <sup>†</sup> [median (IQR)]	NA	17 (9, 34)	NA
Nights with Manual Boluses [n(%)]	158 (25%)	109 (17%)	test not done §
Total Manual Boluses Insulin Units <sup>‡</sup> [median (IQR)]	2.2 (1.3, 4.8)	1.3 (0.6, 2.9)	test not done §
Number of Manual Boluses <sup>‡</sup> [median (IQR)]	1 (1, 1)	1 (1, 1)	NA
Nights with Both Automatic and Manual Boluses [n(%)]	NA	85 (13%)	NA
Total Automatic Boluses Insulin Units* [median (IQR)]	NA	1.8 (0.9, 3.0)	NA
Number of Automatic Boluses* [median (IQR)]	NA	21 (12, 36)	NA
Total Manual Boluses Insulin Units* [median (IQR)]	NA	1.2 (0.6, 2.8)	NA
Number of Manual Boluses* [median (IQR)]	NA	1 (1, 1)	NA
Total Basal and Boluses Insulin Units [median (IQR)]	7.5 (5.2, 10.8)	8.4 (6.0, 12.0)	<0.001

\* One night excluded from all insulin analyses due to missing basal data.

† Among nights with automatic boluses only.

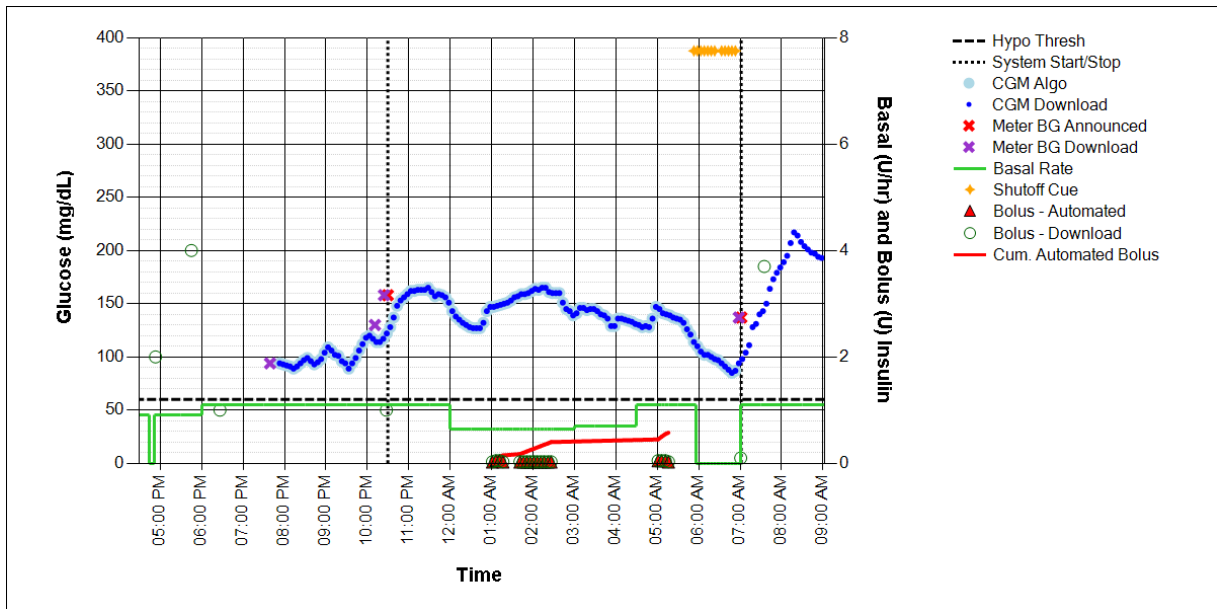
‡ Among nights with manual boluses only.

\* Among nights with both automatic and manual boluses only.

§ Test not of interest and not done.

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**Supplementary Figure S5.** Representative session plot from a night that included both automated correction boluses and automated predictive low-glucose suspend



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**Supplementary Table S6.** Additional Efficacy and Safety Night-Level Secondary Outcomes\*

	<b>PLGS</b>	<b>PHHM</b>	<b>P-value</b>
	<b>Nights</b>	<b>Nights</b>	
# Randomized Nights	641	648	
Hours of Glucose Readings			
<i>median</i>	8.0	8.3	
% Morning with blood glucose <sup>†</sup>			
<60 mg/dL <i>n</i> (%)	2 (<1%)	3 (<1%)	
60 to 69 mg/dL <i>n</i> (%)	5 (<1%)	5 (<1%)	
70 to 180 mg/dL <i>n</i> (%)	421 (66%)	542 (84%)	
181 to 250 mg/dL <i>n</i> (%)	158 (25%)	83 (13%)	
>250 mg/dL <i>n</i> (%)	54 (8%)	15 (2%)	
% Nights with blood ketone $\geq$ 0.6 mmol/L <i>n</i> (%)	3 (<1%)	0 (0%)	NA <sup>‡</sup>
<b>Cumulative Sensor Metrics</b>			
% of nights with glucose level <50 mg/dL for a cumulative duration of			
>5 min <i>n</i> (%)	21 (3%)	29 (4%)	0.20
>60 min <i>n</i> (%)	3 (<1%)	6 (<1%)	NA <sup>‡</sup>
>120 min <i>n</i> (%)	1 (<1%)	4 (<1%)	NA <sup>‡</sup>
>180 min <i>n</i> (%)	1 (<1%)	2 (<1%)	NA <sup>‡</sup>
% of nights with glucose level <60 mg/dL for a cumulative duration of			
>5 min <i>n</i> (%)	64 (10%)	63 (10%)	0.93
>60 min <i>n</i> (%)	19 (3%)	21 (3%)	0.67
>120 min <i>n</i> (%)	2 (<1%)	6 (<1%)	NA <sup>‡</sup>
>180 min <i>n</i> (%)	1 (<1%)	5 (<1%)	NA <sup>‡</sup>
% of nights with glucose level <70 mg/dL for a cumulative duration of			

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	<b>PLGS</b>	<b>PHHM</b>	<b>P-value</b>
	<b>Nights</b>	<b>Nights</b>	
>5 min <i>n</i> (%)	113 (18%)	113 (17%)	0.94
>60 min <i>n</i> (%)	52 (8%)	55 (8%)	0.72
>120 min <i>n</i> (%)	16 (2%)	21 (3%)	0.25
>180 min <i>n</i> (%)	4 (<1%)	9 (1%)	0.002
<b>% of nights with glucose level &gt;180 mg/dL for a cumulative duration of</b>			
>5 min <i>n</i> (%)	418 (65%)	402 (62%)	0.01
>60 min <i>n</i> (%)	323 (50%)	284 (44%)	0.002
>120 min <i>n</i> (%)	254 (40%)	197 (30%)	<0.001
>180 min <i>n</i> (%)	201 (31%)	152 (23%)	<0.001
<b>% of nights with glucose level &gt;250 mg/dL for a cumulative duration of</b>			
>5 min <i>n</i> (%)	163 (25%)	103 (16%)	<0.001
>60 min <i>n</i> (%)	92 (14%)	44 (7%)	<0.001
>120 min <i>n</i> (%)	74 (12%)	31 (5%)	<0.001
>180 min <i>n</i> (%)	48 (7%)	19 (3%)	<0.001
<b>% of nights with glucose level &gt;300 mg/dL for a cumulative duration of</b>			
>5 min <i>n</i> (%)	40 (6%)	26 (4%)	0.02
>60 min <i>n</i> (%)	29 (5%)	11 (2%)	<0.001
>120 min <i>n</i> (%)	17 (3%)	6 (<1%)	<0.001
>180 min <i>n</i> (%)	9 (1%)	2 (<1%)	NA <sup>‡</sup>
<b>Consecutive Sensor Metrics</b>			
<b>% of nights with glucose level &lt;50 mg/dL consecutively for a duration of</b>			
>10 min <i>n</i> (%)	20 (3%)	28 (4%)	0.18
>25 min <i>n</i> (%)	12 (2%)	16 (2%)	0.30

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	<b>PLGS</b>	<b>PHHM</b>	<b>P-value</b>
	<b>Nights</b>	<b>Nights</b>	
>30 min <i>n</i> (%)	9 (1%)	14 (2%)	0.11
>60 min <i>n</i> (%)	3 (<1%)	6 (<1%)	NA <sup>‡</sup>
>120 min <i>n</i> (%)	1 (<1%)	4 (<1%)	NA <sup>‡</sup>
% of nights with glucose level <60 mg/dL consecutively for a duration of			
>10 min <i>n</i> (%)	58 (9%)	57 (9%)	0.86
>25 min <i>n</i> (%)	35 (5%)	43 (7%)	0.30
>30 min <i>n</i> (%)	32 (5%)	38 (6%)	0.38
>60 min <i>n</i> (%)	17 (3%)	16 (2%)	0.73
>120 min <i>n</i> (%)	1 (<1%)	4 (<1%)	NA <sup>‡</sup>
% of nights with glucose level <70 mg/dL consecutively for a duration of			
>10 min <i>n</i> (%)	105 (16%)	108 (17%)	0.74
>25 min <i>n</i> (%)	84 (13%)	84 (13%)	0.99
>30 min <i>n</i> (%)	76 (12%)	76 (12%)	0.97
>60 min <i>n</i> (%)	51 (8%)	46 (7%)	0.51
>120 min <i>n</i> (%)	13 (2%)	15 (2%)	0.49
% of nights with glucose level >180 mg/dL consecutively for a duration of			
>30 min <i>n</i> (%)	366 (57%)	337 (52%)	0.004
>60 min <i>n</i> (%)	316 (49%)	273 (42%)	<0.001
>120 min <i>n</i> (%)	224 (35%)	176 (27%)	<0.001
% of nights with glucose level >250 mg/dL consecutively for a duration of			
>30 min <i>n</i> (%)	116 (18%)	66 (10%)	<0.001
>60 min <i>n</i> (%)	84 (13%)	42 (6%)	<0.001
>120 min <i>n</i> (%)	64 (10%)	24 (4%)	<0.001



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	<b>PLGS</b>	<b>PHHM</b>	<b>P-value</b>
	<b>Nights</b>	<b>Nights</b>	
% of nights with glucose level >300 mg/dL consecutively for a duration of			
>30 min <i>n</i> (%)	32 (5%)	16 (2%)	<0.001
>60 min <i>n</i> (%)	25 (4%)	11 (2%)	<0.001
>120 min <i>n</i> (%)	14 (2%)	4 (<1%)	NA <sup>‡</sup>

\*Glucose results from CGM unless specified as blood glucose.

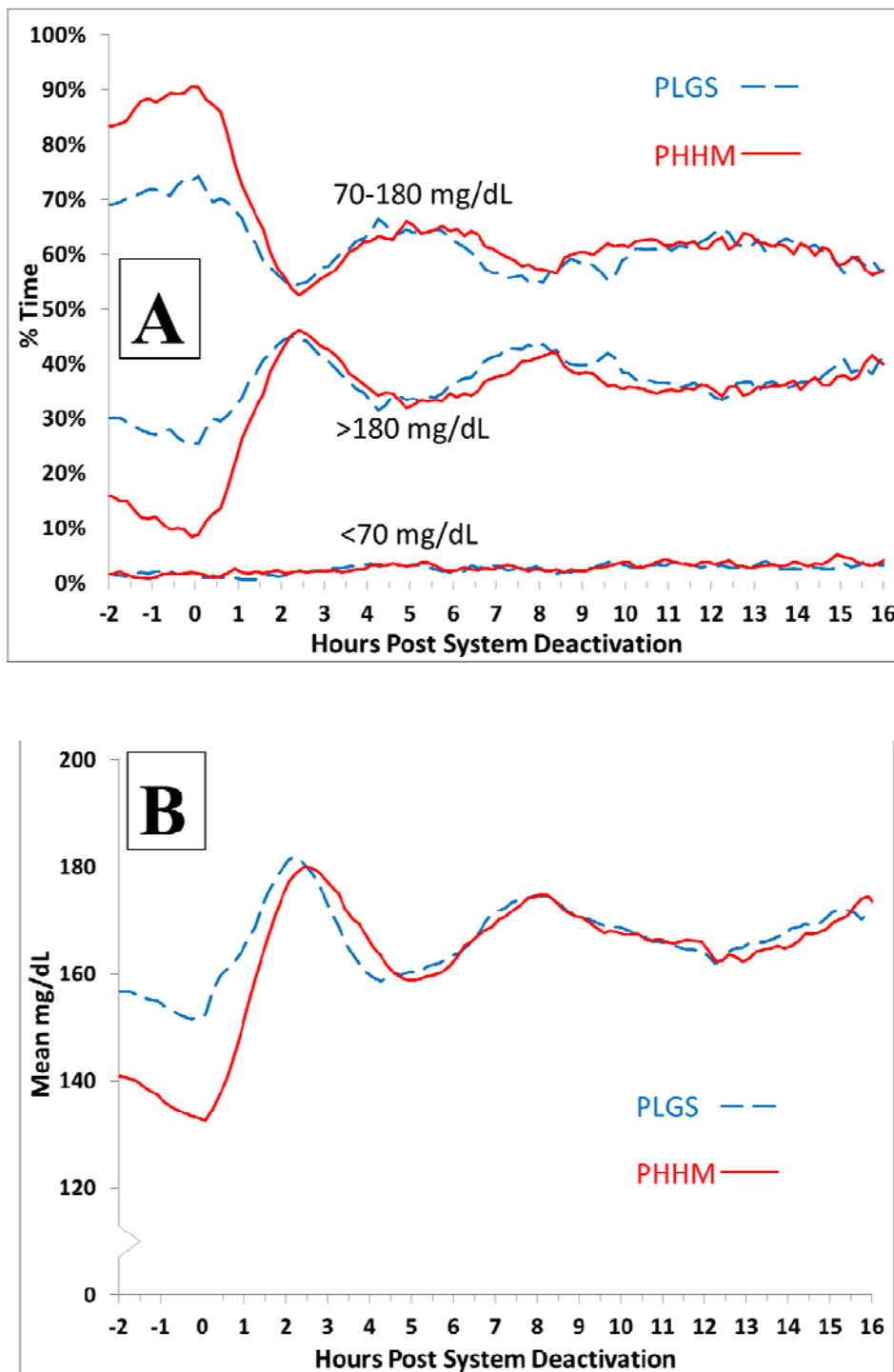
†One PLGS night without morning blood glucose data

‡Too few events for formal statistical comparison

To convert glucose to mmol/L, multiply by 0.0555.

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**Supplementary Figure S7. Percent Time Glucose in Range 70 to 180, Below 70, and Above 180 mg/dL (A) and Mean Glucose (B) after System Deactivation for the Two Treatment Arms**



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**Supplementary Table S8. System Performance Metrics (N=30 Participants)**

	<b>PLGS</b>	<b>PHHM</b>	<b>All</b>
	<b>Nights</b>	<b>Nights</b>	<b>Nights</b>
% Time CGM device functional while controller was active (i.e. readings available in post-hoc device download)	92%	91%	91%
% of available CGM readings obtained by controller			
within 10 minutes of CGM reading	93%	92%	92%
within 20 minutes of CGM reading	97%	97%	97%
% Automatic Bolus Requests Successfully Delivered	NA	95%	NA
% Nights with an Automatic Bolus and a subsequent CGM reading <60 mg/dL <i>n</i> (%)	NA	6 (9%)	NA
Among PLGS nights with CGM >140 mg/dL, % algorithm would have recommended an Automatic Bolus within the prior 2 hr <i>n</i> (%)	78 (79%)	NA	NA
Among PLGS nights when algorithm would have recommended an Automatic Bolus, % with CGM >140 mg/dL within 2 hr of first recommendation <i>n</i> (%)	434 (91%)	NA	NA

To convert glucose to mmol/L, multiply by 0.055