Online Only Supplemental Material

Supplemental 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 6.0 to <15.0 years

3) Glycated hemoglobin level <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 µmol/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

Supplemental Table S2. Participant Characteristics at Enrollment (N=28 Participants) – *medians (IQR)* or *n (%)*

Characteristic	
Age (yrs)	12 (10, 13)
Range	6 to 14
Tanner Stage	
I	10 (36%)
II	8 (29%)
III	4 (14%)
IV	2 (7%)
V	4 (14%)
Male	13 (46%)
Race	
White non-Hispanic	22 (79%)
Hispanic	2 (7%)
Pacific Islander	1 (4%)
Asian	1 (4%)
Black	1 (4%)
More than one	1 (4%)
Diabetes duration (yrs)	4 (3, 7)
Range	1 to 12
Body-mass index (kg/m^2)	17.8 (16.6, 19.8)
Daily insulin dose (U/kg/day)	0.83 (0.75, 0.94)
Enrollment HbA1c (%)	7.6 (7.1, 8.6)
(mmol/mol)	60 (54, 70)
Randomization HbA1c (%)	7.9 (7.2, 8.8)
(mmol/mol)	63 (55, 73)
End of study HbA1c (%)	7.9 (7.3, 8.5)
(mmol/mol)	63 (56, 69)

Supplemental Table S3. Distribution of Shutoff Duration, Pump Suspension, and Automatic Boluses per Night (Nights with ≥ 4 hrs CGM Data, N=28 Participants)

	PLGS Nights	PHHM Nights
# Randomized Nights	600	602
Nights with Pump Suspension *[n(%)]*	431 (72%)	475 (79%)
Glucose At First Shutoff*	N=427	N=472
[*median (IQR)]*	117 (97, 146)	116 (98, 140)
Total Duration of Pump Suspension (min) [*median (IQR)]*	70 (35, 111)	70 (35, 125)
Nights with at least 120 Minutes Suspension during any 150 Minute window *[n(%)]*	33 (8%)	40 (8%)
Nights with a Cumulative 180 Minutes or more Suspension *[n(%)]*	22 (5%)	37 (8%)
Nights with Automatic Boluses *[n(%)]*	NA	500 (83%)
Glucose At First Automatic Bolus**		N=499
[*median (IQR)]*	NA	156 (137, 191)
Cumulative Amount of Boluses Per Night (units)† [*median (IQR)]*	NA	1.10 (0.45, 2.01)
Nights with ≥4 units of Automates Insulin Boluses† *[n(%)]*	NA	24 (4.8%)
Nights with Both Pump Suspension and Automatic Boluses *[n(%)]*	NA	395 (66%)
Cumulative Time Pump was Suspended (min) ‡ [*median (IQR)]*	NA	65 (35, 115)
Cumulative Amount of Boluses Per Night (units) ‡ [*median (IQR)]*	NA	0.95 (0.40, 1.93)

* Glucose data at first shutoff missing for 4 PGLS and 3 PHHM nights.

** Glucose data at first automatic bolus missing for one PHHM night.

† Among nights with automatic boluses only.

‡ Among nights with both pump suspension and automatic boluses.

Supplemental Table S4. Night-Level Secondary Insulin Outcomes (Nights with ≥ 4 hrs CGM Data, N=28 Participants)

	PLGS Nights	**PHHM Nights**	**P-Value**
# Randomized Nights with Complete Insulin Data	600	602	NA
Total Basal Insulin Units *[median (IQR)]*	5.71 (4.19, 8.67)	5.58 (4.22, 8.76)	0.74
Nights with Automatic Boluses *[n(%)]*	NA	500 (83%)	NA
Total Automatic Boluses Insulin Units† *[median (IQR)]*	NA	1.10 (0.45, 2.01)	NA
Number of Automatic Boluses† *[median (IQR)]*	NA	19 (10, 29)	NA
Nights with Manual Boluses *[n(%)]*	251 (42%)	207 (34%)	not done
Total Manual Boluses Insulin Units‡ *[median (IQR)]*	1.60 (0.90, 2.70)	1.10 (0.60, 2.25)	not done
Number of Manual Boluses‡ *[median (IQR)]*	2 (1, 3)	1 (1, 2)	not done
Nights with Both Automatic and Manual Boluses *[n(%)]*	NA	179 (30%)	NA
Total Automatic Boluses Insulin Units• *[median (IQR)]*	NA	1.35 (0.58, 2.05)	NA
Number of Automatic Boluses• *[median (IQR)]*	NA	20 (11, 30)	NA
Total Manual Boluses Insulin Units• *[median (IQR)]*	NA	1.10 (0.60, 2.20)	NA
Number of Manual Boluses• *[median (IQR)]*	NA	1 (1, 2)	NA
Total Basal and Boluses Insulin Units *[median (IQR)]*	6.50 (4.74, 9.44)	7.36 (5.23, 10.90)	<0.001

† Among nights with automatic boluses only.

‡ Among nights with manual boluses only.

• Among nights with both automatic and manual boluses only.

Supplemental Table S5. Additional Efficacy and Safety Night-Level Secondary Outcomes[*]

(N=28 Participants)

	PLGS Nights	**PHHM Nights**	**P-value**
# Randomized Nights	600	602	NA
Hours of Glucose Readings			
median	9.3	9.4	not done
% Morning with blood glucose			not done
<60 mg/dL *n(%)*	1 (<1%)	3 (<1%)	
60-<70 mg/dL *n(%)*	5 (<1%)	2 (<1%)	
70 to 180 mg/dL *n(%)*	347 (58%)	466 (77%)	
>180-250 mg/dL *n(%)*	173 (29%)	93 (15%)	
>250 mg/dL *n(%)*	74 (12%)	38 (6%)	
Cumulative Sensor Metrics			
% of nights with glucose level <50 mg/dL for a cumulative duration of			
>5 min *n(%)*	34 (5.7%)	41 (6.8%)	0.28
>60 min *n(%)*	4 (0.7%)	3 (0.5%)	too few events
>120 min *n(%)*	0 (0.0%)	0 (0.0%)	too few events
>180 min *n(%)*	0 (0.0%)	0 (0.0%)	too few events
% of nights with glucose level <54 mg/dL for a cumulative duration of			
>5 min *n(%)*	47 (7.8%)	53 (8.8%)	0.46
>60 min *n(%)*	5 (0.8%)	7 (1.2%)	too few events
>120 min *n(%)*	2 (0.3%)	0 (0.0%)	too few events
>180 min *n(%)*	0 (0.0%)	0 (0.0%)	too few events
% of nights with glucose level <60 mg/dL for a cumulative duration of			
>5 min *n(%)*	77 (13%)	81 (13%)	0.79
>60 min *n(%)*	14 (2.3%)	11 (1.8%)	too few events
>120 min *n(%)*	4 (0.7%)	1 (0.2%)	too few events
>180 min *n(%)*	1 (0.2%)	0 (0.0%)	too few events
% of nights with glucose level <70 mg/dL for a cumulative duration of			
>5 min *n(%)*	137 (23%)	153 (25%)	0.46
>60 min *n(%)*	36 (6.0%)	39 (6.5%)	0.88
>120 min *n(%)*	9 (1.5%)	9 (1.5%)	too few events
>180 min *n(%)*	6 (1.0%)	3 (0.5%)	too few events
% of nights with glucose level >180 mg/dL for a cumulative duration of			
>5 min *n(%)*	453 (76%)	411 (68%)	0.02
>60 min *n(%)*	346 (58%)	306 (51%)	0.08
>120 min *n(%)*	285 (48%)	229 (38%)	0.003
>180 min *n(%)*	244 (41%)	172 (29%)	<0.001
% of nights with glucose level >250 mg/dL for a cumulative duration of			
>5 min *n(%)*	182 (30%)	117 (19%)	<0.001
>60 min *n(%)*	115 (19%)	56 (9.3%)	<0.001
>120 min *n(%)*	89 (15%)	43 (7.1%)	<0.001
>180 min *n(%)*	68 (11%)	23 (3.8%)	<0.001
% of nights with glucose level >300 mg/dL for a cumulative duration of			
>5 min *n(%)*	54 (9.0%)	35 (5.8%)	0.03
>60 min *n(%)*	30 (5.0%)	18 (3.0%)	0.04

	PLGS Nights	PHHM Nights	P-value
>120 min *n(%)*	22 (3.7%)	9 (1.5%)	<0.001
>180 min *n(%)*	14 (2.3%)	5 (0.8%)	0.001
Consecutive Sensor Metrics			
% of nights with glucose level <50 mg/dL consecutively for a duration of			
>10 min *n(%)*	27 (4.5%)	34 (5.6%)	0.28
>25 min *n(%)*	9 (1.5%)	18 (3.0%)	0.01
>30 min *n(%)*	6 (1.0%)	14 (2.3%)	too few events
>60 min *n(%)*	1 (0.2%)	0 (0.0%)	too few events
>120 min *n(%)*	0 (0.0%)	0 (0.0%)	too few events
% of nights with glucose level <54 mg/dL consecutively for a duration of			
>10 min *n(%)*	33 (5.5%)	43 (7.1%)	0.19
>25 min *n(%)*	15 (2.5%)	25 (4.2%)	0.04
>30 min *n(%)*	10 (1.7%)	20 (3.3%)	0.01
>60 min *n(%)*	5 (0.8%)	4 (0.7%)	too few events
>120 min *n(%)*	1 (0.2%)	0 (0.0%)	too few events
% of nights with glucose level <60 mg/dL consecutively for a duration of			
>10 min *n(%)*	63 (11%)	71 (12%)	0.44
>25 min *n(%)*	38 (6.3%)	43 (7.1%)	0.55
>30 min *n(%)*	30 (5.0%)	35 (5.8%)	0.45
>60 min *n(%)*	8 (1.3%)	6 (1.0%)	too few events
>120 min *n(%)*	3 (0.5%)	1 (0.2%)	0.70
% of nights with glucose level <70 mg/dL consecutively for a duration of			
>10 min *n(%)*	126 (21%)	140 (23%)	0.52
>25 min *n(%)*	84 (14%)	89 (15%)	0.85
>30 min *n(%)*	73 (12%)	78 (13%)	0.75
>60 min *n(%)*	33 (5.5%)	32 (5.3%)	too few events
>120 min *n(%)*	7 (1.2%)	3 (0.5%)	<0.001
% of nights with glucose level >180 mg/dL consecutively for a duration of			
>30 min *n(%)*	388 (65%)	346 (57%)	0.07
>60 min *n(%)*	330 (55%)	290 (48%)	0.08
>120 min *n(%)*	258 (43%)	200 (33%)	<0.001
% of nights with glucose level >250 mg/dL consecutively for a duration of			
>30 min *n(%)*	135 (23%)	80 (13%)	<0.001
>60 min *n(%)*	109 (18%)	52 (8.6%)	<0.001
>120 min *n(%)*	77 (13%)	36 (6.0%)	<0.001
% of nights with glucose level >300 mg/dL consecutively for a duration of			
>30 min *n(%)*	38 (6.3%)	23 (3.8%)	0.04
>60 min *n(%)*	27 (4.5%)	15 (2.5%)	0.02
>120 min *n(%)*	17 (2.8%)	9 (1.5%)	0.02

*Glucose results from CGM unless specified as blood glucose.

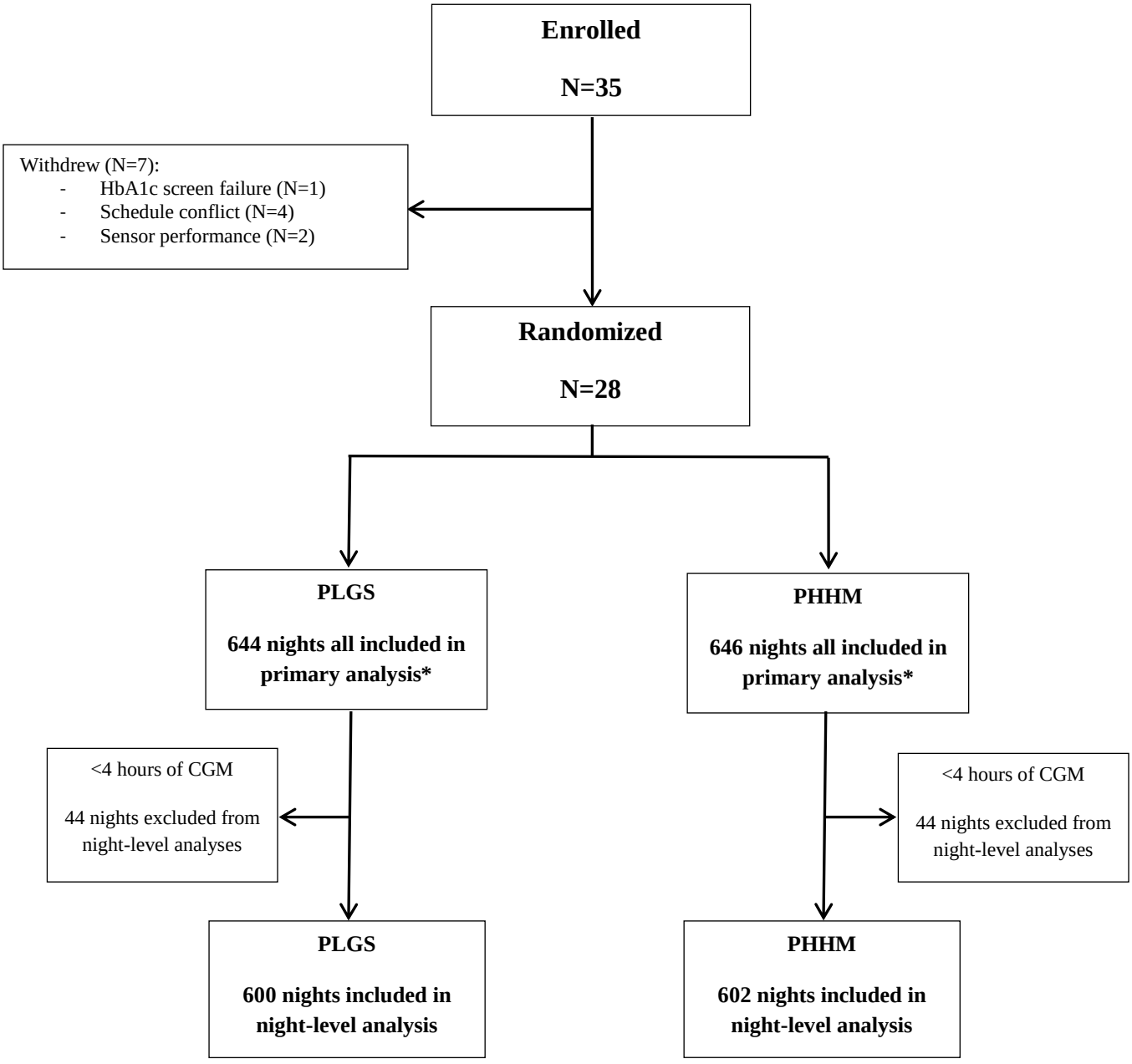
To convert glucose to mmol/L, multiply by 0.0555.

Supplemental Table S6: System Performance Metrics (N=28 Participants)

	PLGS Nights	**PHHM Nights**	**All Nights**
% Time CGM device functional while controller was active (i.e. readings available in post-hoc device download)	90%	90%	90%
% of available CGM readings obtained by controller			
within 10 minutes of CGM reading	94%	94%	94%
within 20 minutes of CGM reading	99%	98%	98%
% Automatic Bolus Requests Successfully Delivered	NA	92%	NA
Nights with at least one Instance of Automated Monitoring Alerts *n(%)*			
Low CGM	44 (7%)	56 (9%)	100 (8%)
High CGM	0 (0%)	0 (0%)	0 (0%)
Large Bolus	0 (0%)	3 (<1%)	3 (<1%)
Lost Communication	7 (1%)	9 (1%)	16 (1%)
Missing CGM	0 (0%)	0 (0%)	0 (0%)
Among PLGS nights with CGM ≥140 mg/dL, % algorithm would have recommended an Automatic Bolus within the prior 2 hr *n(%)*	57 (81%)	NA	NA
Among PLGS nights when algorithm would have recommended an Automatic Bolus, % with CGM ≥140 mg/dL within 2 hr of first recommendation *n(%)*	452 (95%)	NA	NA

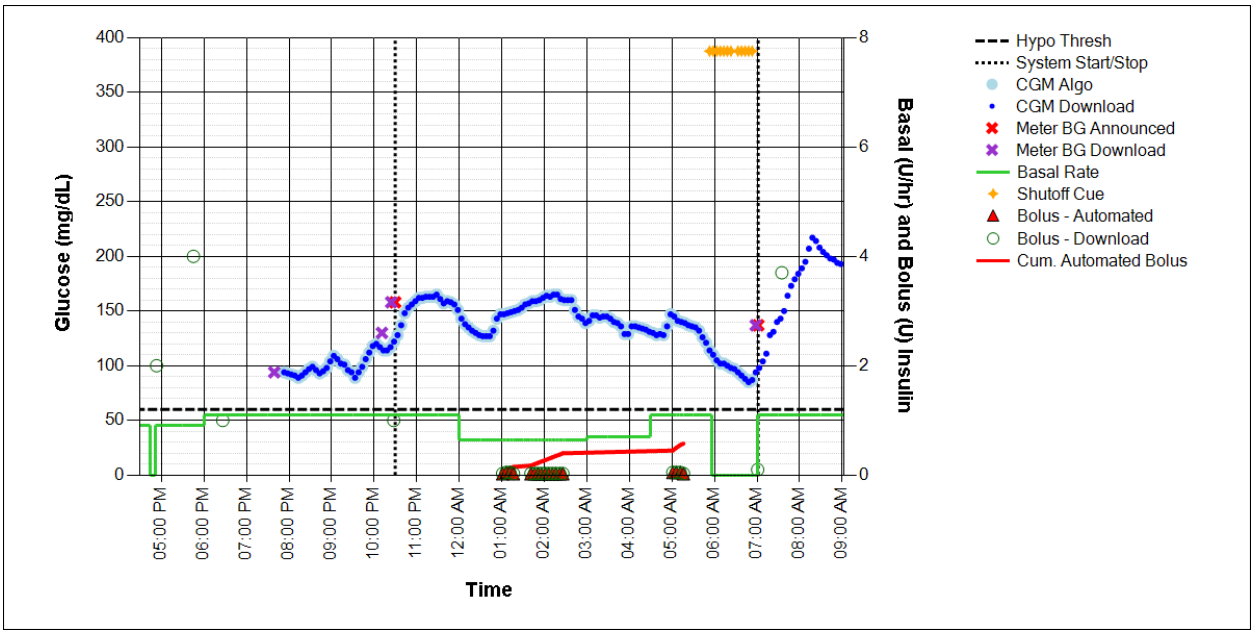
To convert glucose to mmol/L, multiply by 0.0555.

Supplemental Figure S1. Study Flowchart

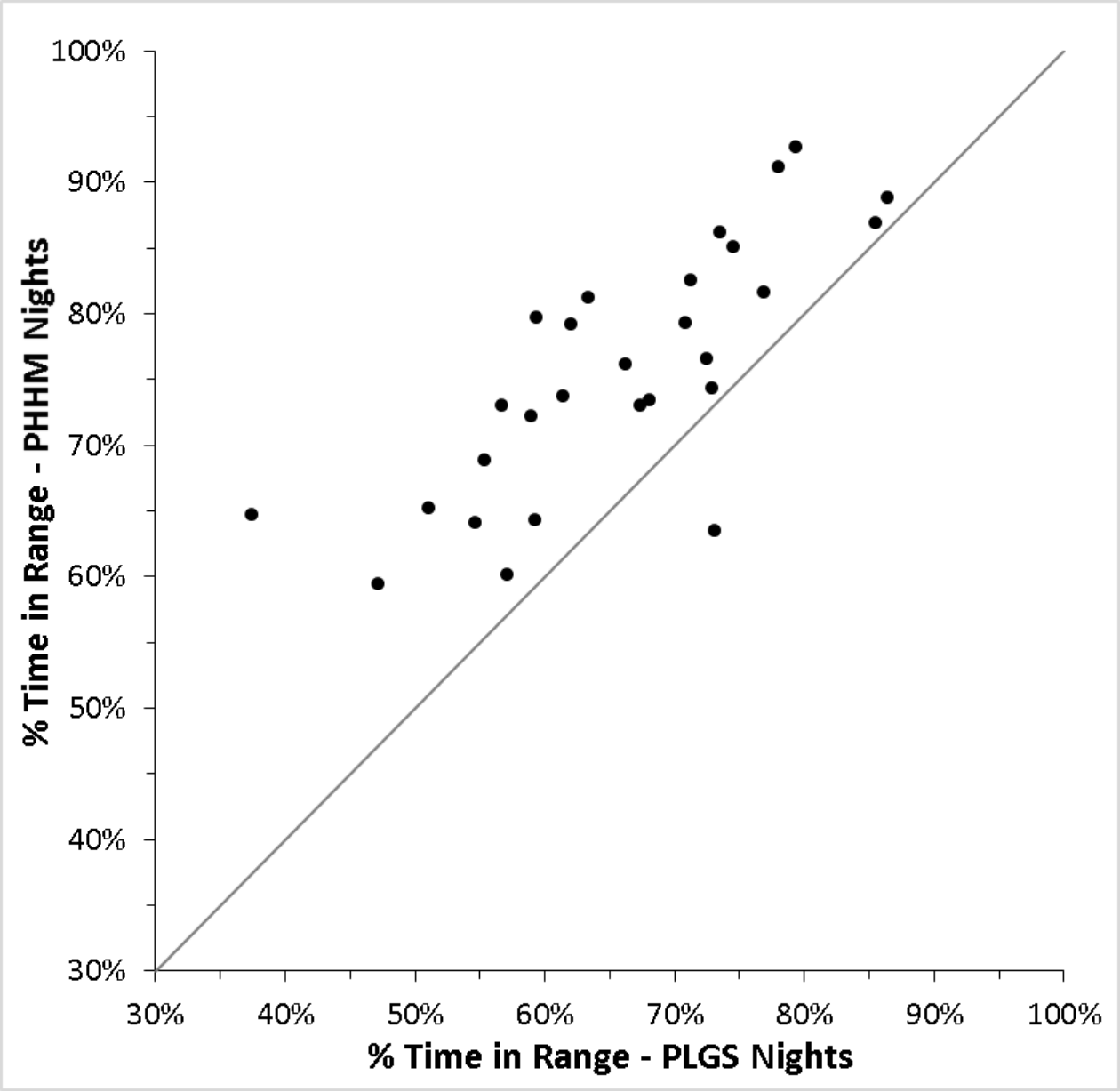


* There were 11 (PLGS) and 15 (PHHM) randomized nights with no CGM data at all.

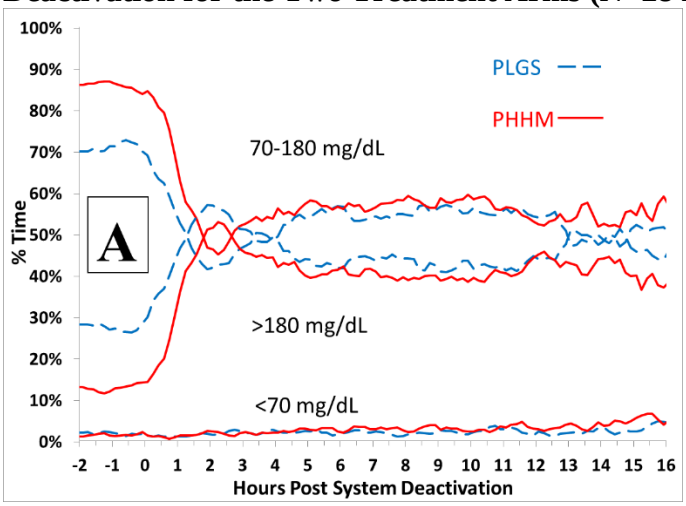
Supplemental Figure S2. Representative session plot from a night that included both automated correction boluses and automated predictive low-glucose suspend

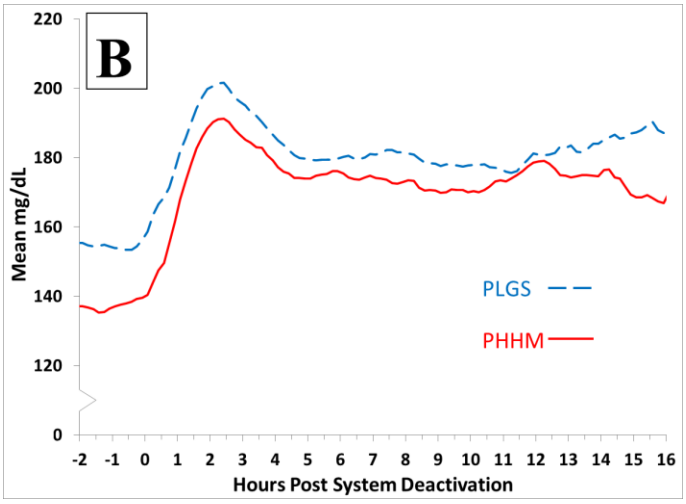


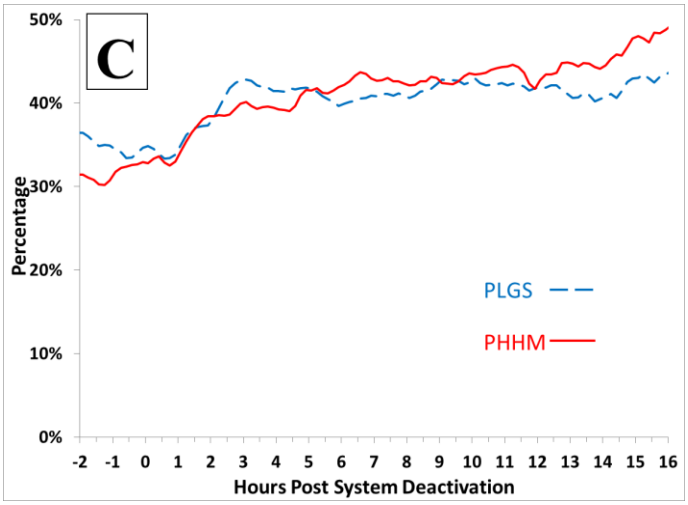
Supplemental Figure S3. Percent Time Glucose in the Range 70 to 180 mg/dL by Treatment Arm (N=28 Participants). The diagonal represents the line of identity.



Supplemental Figure S4. Percent Time Glucose in Range 70 to 180, Below 70, and Above 180 mg/dL (A), Mean Glucose (B), and Coefficient of Variation (C) after System Deactivation for the Two Treatment Arms (N=28 Participants)






C
50%
40%
30%
20%
10%
0%
Percentage
-2 -1 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
Hours Post System Deactivation
PLGS
PHHM