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Interpretation of Continuous Glucose Monitoring (CGM) Data

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Overview of CGM

- Continuous glucose monitoring provides glucose data every few minutes from an interstitial fluid reading
- The first device was approved in the United States in 1999 as a retrospective, blinded to the patient device
- New devices on the market and coming to the market have been significantly improved for ease of use, accuracy, and real-time diabetes management
- Readings can now be used for both real-time, in the moment decisions and retrospectively for pattern management

Bailey, T.S., Grunberger, G., Bode, B.W., Handelsman, Y., Hirsch, I.B., Jovanovic, L., Roberts, V.L., Rodbard, D., Tamborlane, W.V. and Walsh, J. (2016). American Association of Clinical Endocrinologists and American College of Endocrinology 2016 Outpatient Glucose Monitoring Consensus Statement. *Endocrine Practice*. 22 (2), 231-261.

Walsh, J., Roberts, R. (2013). *Pumping Insulin* (5th Edition). Torrey Pines Press. San Diego, CA.



Advantages of CGM?

- Fewer hypoglycemic events while lowering A1c values
- Reduction in severity of hypoglycemic events
- Less glycemic variability
- Decreased anxiety over blood sugar levels
- Improved quality of life

Bailey, T.S., Grunberger, G., Bode, B.W., Handelsman, Y., Hirsch, I.B., Jovanovic, L., Roberts, V.L., Rodbard, D., Tamborlane, W.V. and Walsh, J. (2016). American Association of Clinical Endocrinologists and American College of Endocrinology 2016 Outpatient Glucose Monitoring Consensus Statement. *Endocrine Practice*. 22 (2), 231-261.

Kaufman, F.R., Westfall, E. (2012). *Insulin pumps and continuous glucose monitoring: A User's guide to effective diabetes management*. American Diabetes Association. Alexandria, VA.

Rodbard, D. (2016). Continuous glucose monitoring: A review of successes, challenges, and opportunities. *Diabetes Technology & Therapeutics*. 18 (2), S2-3.

Schiener, G. (2015). *Practical CGM: A Guide to Improving Outcomes through Continuous Glucose Monitoring*. American Diabetes Association. Alexandria, VA.

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Polling Question

Continuous glucose monitors have become so accurate that patients do not ever have to question the results.

- A) True
- B) False

CGM Drawbacks/Barriers

- Expense
 - as of 2/2016, no coverage for elderly people with T1DM
- Calibration
- Accuracy
- Convenience
- Fingerstick prior to treatment
- Patient acceptance
- Clinical inertia
- Sensor lifetime
- User experience/knowledge

Rodbard, D. (2016). Continuous glucose monitoring: A review of successes, challenges, and opportunities. *Diabetes Technology & Therapeutics*. 18 (2), S2-3.



Thoughts from Consensus Committee

- “The truth is that I go through it every day in the office. Yes, it looks a bit intimidating, but because patients now demand better control and achieve better control, it is impossible to maintain an HbA1c below 7% without having CGM,” said Dr. Victor Roberts.
- “A series of studies that looked at CGM showed that the more patients wear them, the more likely they are to stay in control. The CGM is a video of what is going on, but a blood draw is just a picture. The patient gets a visual of the situation instead of a snapshot. Patients take well to it. The majority of the patients are not well-controlled and this is a powerful tool to get there and stay there,” he added.

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Thoughts from Consensus Committee

- The consensus statement states that many pediatric patients with type 1 diabetes may be candidates for CGM, especially if they and their family caregivers have the appropriate training. Although no strong evidence indicates that using CGM will allow a patient to live longer, it is likely they will have better quality of life.
- They feel better, they aren't victimized as much. They are in control and they are less likely to be depressed.

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Research

- Due to the increasing demand for technology and the rapid release of newer and better models, it is hard to have up-to-date research that matches the pace of today's technology
- Research on today's models will most likely not be released for 3-4 years
- The Consensus Statement recommends CGM for Type 1 Diabetes, both for adult and pediatric ages
 - Trials assessing the use of CGM in type 2 patients are ongoing

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Schiener, G. (2015). Practical CGM: A Guide to Improving Outcomes through Continuous Glucose Monitoring. American Diabetes Association. Alexandria, VA.



Polling Question

How much effect can acetaminophen have on CGM results?

- A) None really; this is just a safety disclaimer from the companies.
- B) It depends on where the sensor has been inserted.
- C) Can result in significantly false high glucose readings



Factors to Consider when Interpreting CGM Data

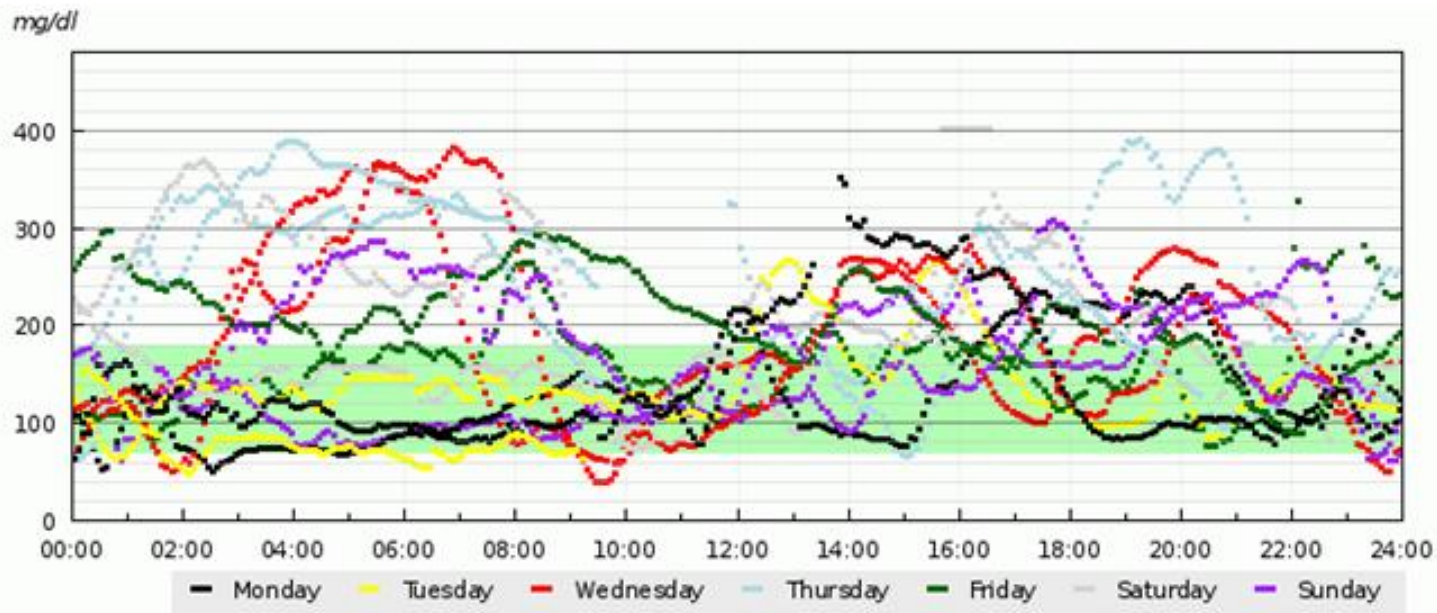
- Alcohol
- Stress
- Menses
- New meds
- Acetaminophen
- Change in physical activity/season
- Times are set correctly
- Type of meter used for calibration
- Growth spurts/puberty
- Sleep position

Basu, A., Veetil, S., Dyer, R., Peyser, T., and Basu, R. (2016). Direct evidence of acetaminophen interference with subcutaneous glucose sensing in humans: A pilot study. *Diabetes Technology and Therapeutics*. 18 (2), S2-43-47.

Bailey, T.S., Grunberger, G., Bode, B.W., Handelsman, Y., Hirsch, I.B., Jovanovic, L., Roberts, V.L., Rodbard, D., Tamborlane, W.V. and Walsh, J. (2016). American Association of Clinical Endocrinologists and American College of Endocrinology 2016 Outpatient Glucose Monitoring Consensus Statement. *Endocrine Practice*. 22 (2), 231-261.

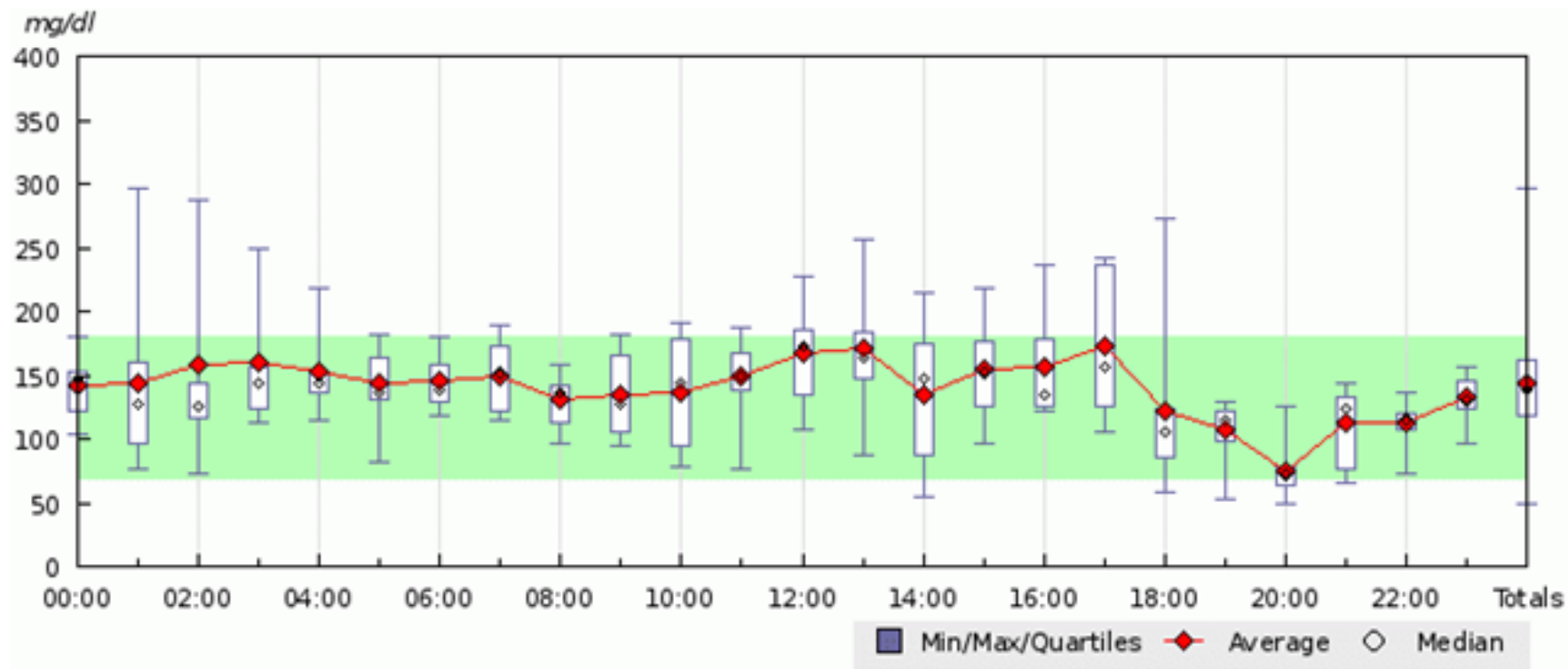
Pattern Management

The “spaghetti report” (Standard Day)



Show active basal profile

Number of values: 3631	Values above goal (180 mg/dl): 1557	Highest value (mg/dl): 401 (09/10/2016 16:32)
Values per day: 259.4	Values within goal (70-180 mg/dl): 1966	Lowest value (mg/dl): 39 (09/14/2016 09:37)
Period average (mg/dl): 178	Values below goal (70 mg/dl): 108	Standard deviation: 78



Compilation

Glucose	CGM	Insulin	Carbs	Activity	
Average 133 mg/dl	Average 134 mg/dl	Average daily dose 25.3 U	Average carbs / day 114 g	Avg steps / day 0 steps	Avg kcal / day 0 kcal
SD = 42 # = 42	SD = 30 # = 1953	SD = 4 # days = 7	SD = 37 # = 20	0% of 10000 (target)	0% of 2500 (target)
Avg # / day = 6	Avg # / day = 279	Avg # bolus doses/day = 6.9	Avg # / day = 2.9		

Glucose (mg/dl)

Glucose values summary		Interval	Avg BG	# BG	SD
Average (mg/dl)	133	00:00-06:00	173	6	22
Median (mg/dl)	126	06:00-08:00	130	1	0
Highest value (mg/dl)	240	08:00-10:00	115	5	8
Lowest value (mg/dl)	70	10:00-12:00	132	3	24
Standard deviation (SD)	42	12:00-14:00	94	6	8
Values per day	6	14:00-16:00	146	4	44
Number of values	42	16:00-18:00	114	2	7
Values above goal (180 mg/dl)	8	18:00-20:00	137	6	28
Values within goal (70-180 mg/dl)	34	20:00-22:00	117	3	53
Values below goal (70 mg/dl)	0	22:00-24:00	147	6	64



CGM (mg/dl)

CGM readings summary		Interval	Avg	#	SD
Average (mg/dl)	134	00:00-06:00	151	509	30
Median (mg/dl)	130	06:00-08:00	126	169	13
AUC high > 180 mg/dl	2	08:00-10:00	125	162	13
AUC low < 70 mg/dl	0	10:00-12:00	131	149	20
Highest value (mg/dl)	248	12:00-14:00	117	162	25
Lowest value (mg/dl)	63	14:00-16:00	129	171	33
Standard deviation (SD)	30	16:00-18:00	127	156	20
Values per day	279	18:00-20:00	125	167	26
Number of values	1953	20:00-22:00	131	173	33
Values above goal (180 mg/dl)	184	22:00-24:00	146	173	46
Values within goal (70-180 mg/dl)	1768				
Values below goal (70 mg/dl)	1				
Average daily CGM sensor duration	23:15 (97%)				
Total CGM sensor duration	6 days 18:45				



Insulin

Insulin doses summary		Bolus calculation summary	
Average daily insulin (U)	25.3	Avg # ezBG Boluses/day	3.3 (48%)
Standard deviation (SD)	4.2	Avg # ezCarb Boluses/day	2.9 (42%)
Average daily basal (U)	12.6	Avg # Combo Boluses/day	0 (0%)
Average daily bolus (U)	12.7	Avg # Normal Boluses/day	0.7 (10%)
Average bolus doses/day	6.9	Bolus overrides/total boluses	6%
Average days between cannula fills	3	Avg # bolus overrides/day	0.4
Average days between primes	1	Avg # bolus ezBG overrides/day	0.4
		Avg # bolus ezCarb overrides/day	0
		Avg # carbs/ezCarb Bolus	40 g
		Avg # Insulin Units/ezCarb Bolus	3

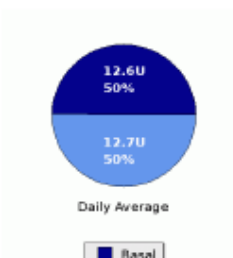
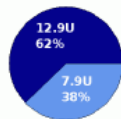


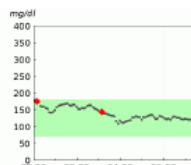
Figure 1 is a dual-axis chart showing Basal and Bolus insulin levels over a 24-hour period. The x-axis represents time from 00:00 to 24:00. The left y-axis represents Basal (Units/Hour) from 0.00 to 0.70. The right y-axis represents Bolus (Units) from 0.0 to 8.0. The Basal insulin (blue line) starts at 0.55 units/hour, drops to 0.50 units/hour at 10:00, and then to 0.45 units/hour at 12:00. The Bolus insulin (orange bars) shows three doses: 0.0 units at 08:00, 4.5 units at 08:00, and 3.4 units at 18:00.

Time	Basal (Units/Hour)	Bolus (Units)
00:00	0.55	0.0
02:00	0.55	0.0
04:00	0.55	0.0
06:00	0.55	0.0
08:00	0.55	4.5
10:00	0.50	0.0
12:00	0.45	0.0
14:00	0.45	0.0
16:00	0.45	0.0
18:00	0.45	3.4
20:00	0.45	0.0
22:00	0.45	0.0
24:00	0.55	0.0

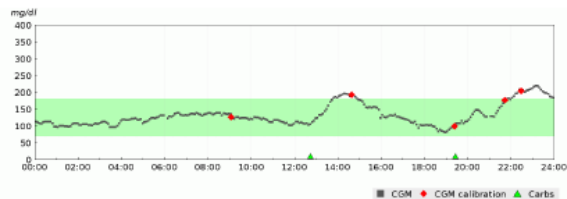
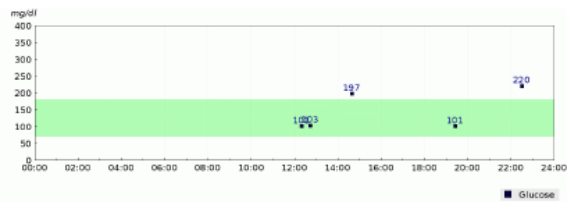


Basal		Bolos	
Time	U/h	Time	U
00:02	0.575	00:10	0.60
10:02	0.525		
13:02	0.500	Override (Suggested: 0.25)	
22:02	0.550	(Corr: 1.10)	
		(IOB: 0.83)	
		03:09	0.00
		07:52	4.50
		(Meal: 4.50)	
		10:04	0.00
		(IOB: 0.74)	
		18:43	3.35
		(Meal: 3.33)	

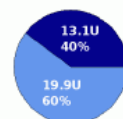
Time (h)	Glucose (mg/dl)	Patient ID
00:00	154	154
03:00	140	140
08:00	130	130
10:00	142	142
18:00	138	138



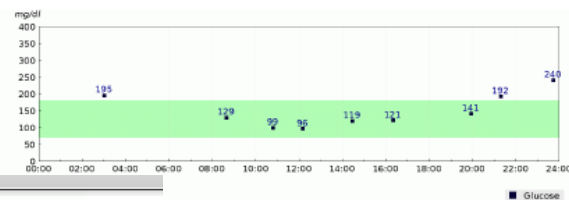
Time (Hour)	Basal (Units/Hour)	Bolus (Units)
00:00 - 10:00	0.55	0.0
10:00 - 22:00	0.50	1.4
22:00 - 24:00	0.65	2.6



Time	Basal (Units/Hour)	Bolus (Units)
00:00	0.55	0.0
02:00	0.55	1.9
04:00	0.55	0.0
06:00	0.55	0.0
08:00	0.55	2.0
10:00	0.55	0.0
12:00	0.55	2.2
14:00	0.55	0.0
16:00	0.55	2.4
18:00	0.55	3.0
20:00	0.55	3.0
22:00	0.55	1.6
24:00	0.55	2.8



Basal		Bolos	
Time	U/h	Time	U
20:14	0.000	03:01	1.85
20:29	0.550	(Corr: 1.87)	
		08:39	2.00
		(Meal: 2.00)	
		10:48	0.00
		(IOB: 0.35)	
		12:11	2.25
		(Meal: 2.26)	
		14:27	0.00
		(IOB: 0.32)	
		16:20	2.35
		(Meal: 2.33)	

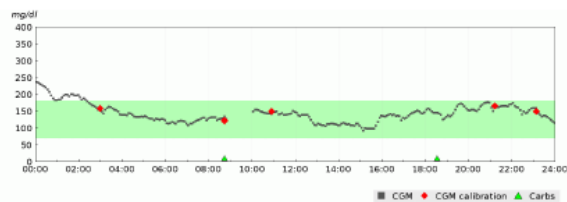
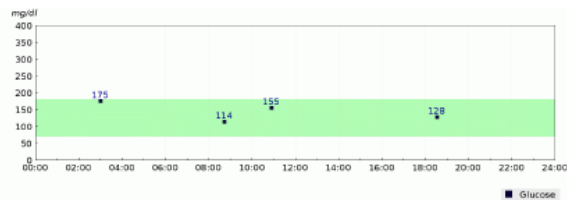


Time (Hour)	Basal (Units/Hour)	Bolus (Units)
00:00 - 12:00	0.55	0.0
03:00	0.55	1.4
09:00	0.55	3.6
10:00	0.55	0.3
12:00 - 22:00	0.50	0.0
19:00	0.50	2.2
22:00 - 24:00	0.55	0.0

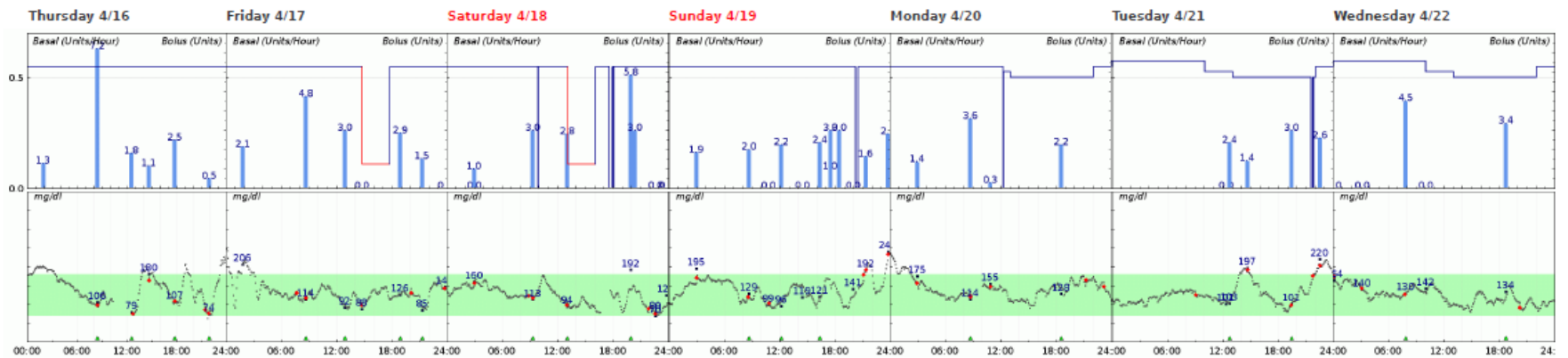


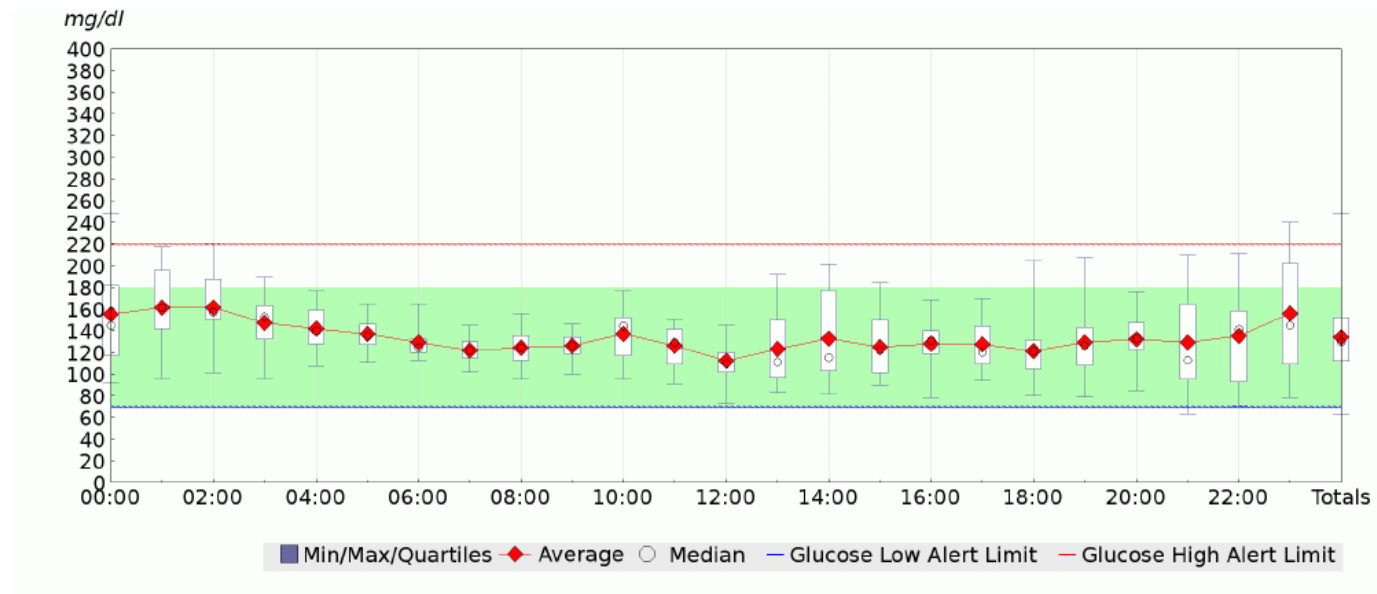
Basal		Bolus	
Time	U/h	Time	U
12:17	0.000	03:00	1.35
12:20	0.525	(Corr:	1.37)
13:02	0.500	08:44	3.60
22:02	0.550	(Meal:	3.60)
		10:54	0.30
		(Corr:	0.87)
		10:08	0.59)
		18:33	2.25
		(Meal:	2.26)

Carbohydrates	
Time	
08:44	36g
18:33	34g



Comparison : Day by day overview



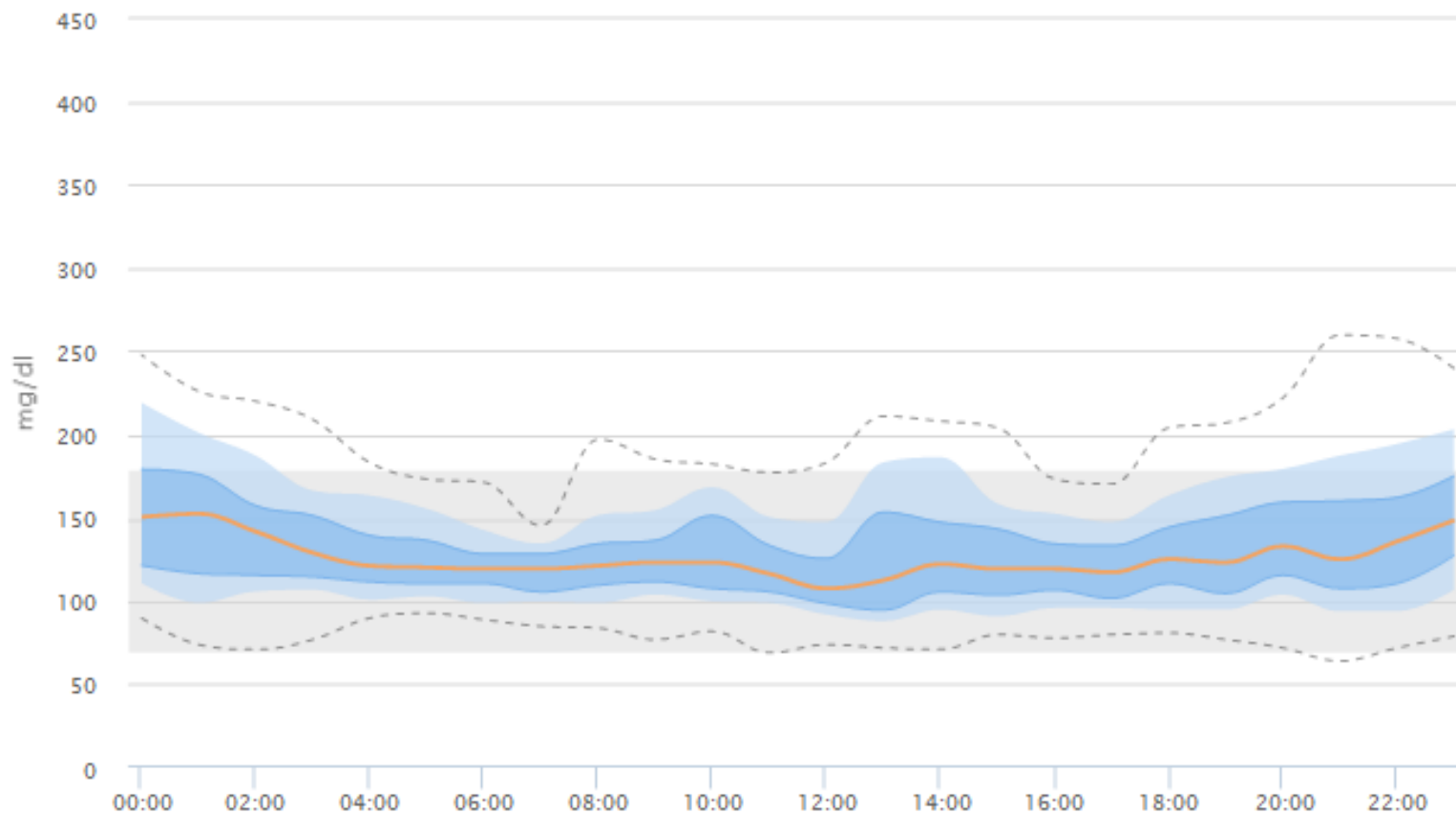


Statistics

Number of values: 1953
Values per day: 279
Period average (mg/dl): 134

Values above goal (180 mg/dl): 184
Values within goal (70-180 mg/dl): 1768
Values below goal (70 mg/dl): 1

Highest value (mg/dl): 248 (04/17/2015 00:03)
Lowest value (mg/dl): 63 (04/16/2015 21:43)
Standard deviation: 30



Show active basal profile

Number of values: 7618	Values above goal (180 mg/dl): 573	Highest value (mg/dl): 260 (05/11/2015 21:51)
Values per day: 253.9	Values within goal (70-180 mg/dl): 7042	Lowest value (mg/dl): 63 (04/16/2015 21:43)
Period average (mg/dl): 131	Values below goal (70 mg/dl): 3	Standard deviation: 30

Pattern Management

After downloading CGM data assess for patterns in the following manner:

- **Step 1:** Assess overnight glucose patterns. Make changes based upon a pattern of values.
- **Step 2:** Assess glucose patterns for pre-prandial period. Make changes based upon a pattern of values for each individual mealtime.
- **Step 3:** Assess glucose patterns for post-prandial period. Make changes based upon a pattern of values for each individual mealtime.



Hypoglycemia Review

Time Period	Considerations	Possible Actions*
If seen in the overnight period (12am-6am)	<ul style="list-style-type: none">• Is the basal too high?• Was there a change in activity within last 24 hours?• Was the site changed at bedtime?• Was a correction given before bed or during night?	<ul style="list-style-type: none">• Adjust the basal rate• Recommend a temporary basal overnight when increased activity• Recommend routine site changes earlier in the day• Assess insulin sensitivity factor (ISF) and if a different ISF needed at this time

*Must be individualized to each patient.

Hypoglycemia Review

Time Period	Considerations	Possible Actions*
If seen in the pre-meal period (before snack/meal)	<ul style="list-style-type: none"> • Are carbs being counted correctly? • Was there a change in normal activity after last meal? • Assess the timing of the meal bolus • Assess the type/amount of previous bolus • Is the Insulin to Carb (IC) ratio too high? • Is the ISF too high? • Assess the timing/quantity/composition of previous meal • Is the Insulin On Board (IOB) set correctly? 	<ul style="list-style-type: none"> • Provide a carb counting refresher • Reduce the amount of a bolus if activity will follow the meal • Adjust the timing of the meal bolus • May need to adjust the type of previous bolus • Adjust IC ratio • Adjust ISF • Evaluate if an extended or combo bolus may be more effective • Test for IOB duration

*Must be individualized to each patient.

Hyperglycemia Review

Time Period	Considerations	Possible Actions*
If seen in the overnight period (12am-6am)	<ul style="list-style-type: none"> • Are carbs being counted correctly? • Was there a bedtime snack without coverage? • Is the basal too low? • Was the site changed at bedtime? • How long since last site change? • Is there gastroparesis? • Is the auto-off feature enabled on the pump? 	<ul style="list-style-type: none"> • Provide a carb counting refresher • Consider covering snack with a bolus • Adjust the basal rate • Recommend routine site changes earlier in the day, check 1-2 hours after any site change • Assess if changing sites frequently enough • Assess if last meal of day could be impacting BGs during this time period • Instruct the patient how to avoid an auto-off shutdown, evaluate time period set for shutdown

*Must be individualized to each patient.

Hyperglycemia Review

Time Period	Considerations	Possible Actions*
If seen in the pre-meal period (before snack/meal)	<ul style="list-style-type: none"> • Assess the timing of the previous bolus • Assess the type/amount of previous bolus • Assess the timing/quantity/composition of previous meal • Was there activity after last meal (counter-regulatory effect)? • Is there any dawn phenomenon (before breakfast)? • Is IC ratio too high? • Is the ISF too high? 	<ul style="list-style-type: none"> • May need to adjust timing of previous bolus • May need to adjust the type of previous bolus • Evaluate if an extended or combo bolus may be more effective • Consider using a + temp basal during/after activity • Adjust basal rate • Adjust IC ratio • Adjust ISF

*Must be individualized to each patient.

Hyperglycemia Review

Time Period	Considerations	Possible Actions*
If seen in the post-meal period (3-hour period after meal)	<ul style="list-style-type: none"> • Are carbs being counted correctly? • Assess the timing of previous bolus • Assess the type/amount of previous bolus • Assess the timing, quantity, composition of previous meal • Was an extended or combo bolus used? • Was there any activity prior to meal (counter-regulatory effect)? • Is the IC ratio too low? • Is the ISF too low? • Is there any gastroparesis? 	<ul style="list-style-type: none"> • Provide a carb counting refresher • Adjust timing of the previous bolus • May need to adjust the type of previous bolus • Evaluate if an extended or combo bolus may be more effective • Alter the type, percentage, or duration of bolus • Consider using a +temp basal during/after activity • Adjust IC ratio • Adjust ISF • Consider using a combo/extended bolus

*Must be individualized to each patient.

Polling Question

According to the *Variability of Insulin Requirements Over 12 Weeks of Closed-Loop Insulin Delivery in Adults with Type 1 Diabetes* study, what time of the day showed the most variability of total daily insulin requirements over a prolonged period in adults with type 1 diabetes?

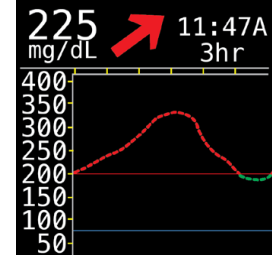
- A) Overnight requirements
- B) Daytime requirements
- C) Total daily insulin requirements

Consideration for Therapy Adjustment Using Trend Arrows When Bolusing

When using trending arrows to help adjust the bolus dose, you should consider the following:

- Hypoglycemia
- Time of insulin in relation to food
- The greater the velocity of change indicated by the arrows, the earlier or more aggressive the action should be
- Insulin on board
- Direction of the trend
- Type of food consumed (simple vs. complex carb, high fat, high protein)
- Change in activity level and past response to activity
- Honeymoon stage

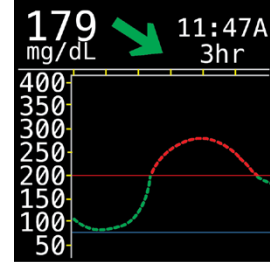
Trend Arrows and Insulin Adjustments



Glucose Trend	Possible Actions
Glucose rising (>3mg/dl/min)	<ul style="list-style-type: none"> • Take pre-meal bolus insulin and delay eating until the sugar is leveled out • Adjust correction dose by increasing recommended dose 20%
Glucose rising (2-3mg/dl/min)	<ul style="list-style-type: none"> • Take pre-meal bolus insulin and delay eating until the sugar is leveled out • Adjust correction dose by increasing recommended dose 10%
Glucose rising (1-2mg/dl/min)	<ul style="list-style-type: none"> • Take pre-meal bolus insulin and delay eating until the sugar is leveled out
Glucose rising/falling (<1mg/dl/min)	<ul style="list-style-type: none"> • Take bolus as recommended for carbs

*Must be individualized to each patient.

Trend Arrows and Therapy Adjustments

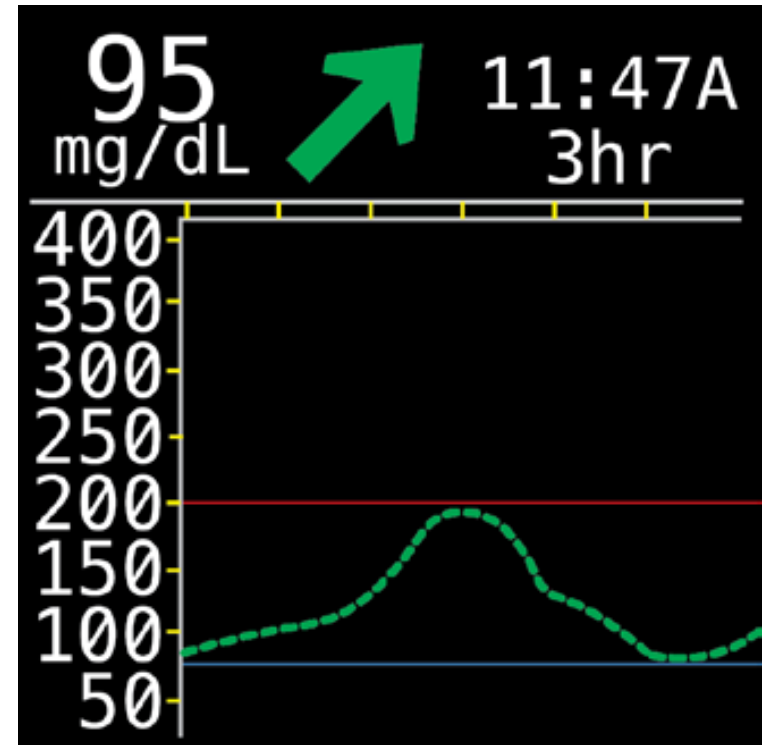
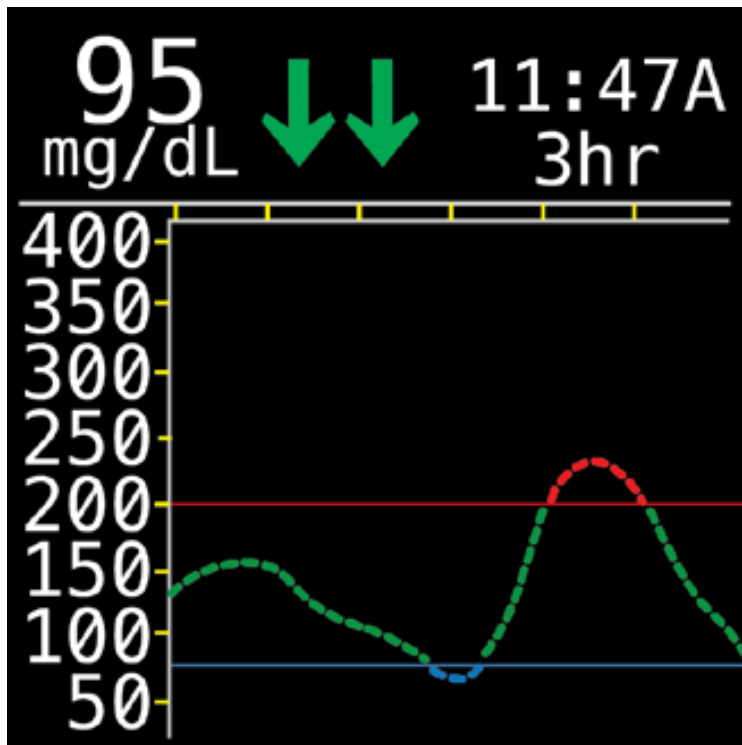


Glucose Trend	Possible Actions
Glucose falling (1-2mg/dl/min)	<ul style="list-style-type: none"> • If in lower end of target range, follow the rule of 15
Glucose falling (>2-3mg/dl/min)	<ul style="list-style-type: none"> • If in the lower end of target range, follow the rule of 15 • Adjust meal bolus by decreasing recommended dose 10% • Set a temporary basal if appropriate (activity)
Glucose falling (>3mg/dl/min)	<ul style="list-style-type: none"> • If in the lower end of target range, follow the rule of 15 • Adjust meal bolus by decreasing recommended dose 20% • Set a temporary basal if appropriate (activity)

*Must be individualized to each patient.

Study results

CGM users often rely on rate of change (ROC) information when determining insulin doses and tend to make larger changes than current recommendations suggest regardless of insulin delivery methods.



Pettus, J. and Edelman, S.V. (2016). Use of glucose rate of change arrows to adjust insulin therapy among individuals with type 1 diabetes who use continuous glucose monitoring. *Diabetes Technology & Therapeutics*. 18 (2), S2-34.

Conclusion

- “CGM offers the potential to revolutionize patient treatment by providing more frequent information that may allow a greater portion of patients to achieve target glucose and A1C levels with greater safety.”
- “CGM is only as beneficial as the patient’s desire and ability to use it.”

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References

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