Glucose Management and the Actual Pump Practices Study

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Toronto, ON
June 22, 2012

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Many Thanks

To

Medtronic of Canada Ltd.,
Sarrah Morris, BScN, RN, MBA,

and especially Sandi Williams, M.Ed, RD, CDE,
Trixie Williams, R.N., BScN, MHS,
and the diabetes clinical staff at St. Michael's Hospital

Disclosure

- Book sales – all pump companies
- Advisory Boards – Tandem Diabetes, Unomedical, Halozyme, AgaMatrix, PicoLife Technologies
- Consultant – Bayer, Roche, BD, Abbott, Tandem Diabetes, Acon Laboratories
- Speakers Bureau – Tandem Diabetes
- Sub-Investigator – Glaxo Smith Kline, Animus, Sanofi-Aventis, Bayer, Biodel, Dexcom, Novo Nordisk
- Pump Trainer – Accu-Chek, Animas, Medtronic, Omnipod
- Web Advertising – Sanofi-Aventis, Sooil, Medtronic, Animas, Accu-Chek, Abbott, etc.

What We'll Cover

- Glucose Management Overview – In Part 1
- Actual Pump Practices Study Results – In Part 1
- Bolus Calculator Settings – Part 2
- BOB, DIA, and Insulin Stacking – Part 3
- Infusion Set Issues – Part 4
- CGMs for Better Control – Part 5

Terms

- **TDD** – total daily dose (all basals and boluses) of insulin
- **Basal** –background insulin released slowly through the day
- **Bolus** – a quick release of insulin – Carb boluses cover carbs and Correction boluses lower high readings
- **Bolus Calculator (BC)** – what calculates bolus recommendations
- **Correction Target** – the BG aimed for with correction bolus
- **Bolus On Board (BOB)** – bolus insulin still active from recent boluses, active insulin, insulin on board
- **Duration of Insulin Action (DIA)** – how long a bolus will lower the BG – used to measure BOB

Glucose Management

Dose For Success

1. Stop lows first
2. Find an improved TDD – gives normal, stable BGs
3. Set & test basals – keeps overnight readings level
4. Set & test CarbF – fine-tune premeal BGs
5. Lower post meal BGs – bolus early, low GI foods, GLP-1 agonists, Symlin, acarbose, etc.
6. Set & test CorrF – bring highs down safely

Enjoy good control or return to #1

Brittle diabetes or frequent highs usually = wrong settings

Don't Compound Errors

Every error in settings or action **MAGNIFIES** the total dosing error!

Settings:
- Basal rates
- CarbF
- CorrF
- DIA/insulin stacking
- Correction target
- Meter accuracy

Actions:
- Carb counts
- Glucose monitoring
- Activity
- Menses, stress, pain, etc.
- Accounting for BOB

The "Other Things" Needed

- Check glucose 6 x a day or wear a CGM
- Use the bolus calculator for all boluses
- Cover all carbs with a bolus before eating, unless there's a good reason not to
- When low, don't over-treat with carbs
- When high, don't over-treat with insulin
- Don't give blind boluses

Size Up the Glucose Problem

- If it ain't broke, don't fix it!
- **Severe** – An improved TDD (iTDD) will correct most major glucose problems once new settings are selected from the iTDD
- **Moderate** – use pattern management to fine tune doses and pump settings
- **Mild** – tweak pump settings

Therapy Guides

TDD – Raise for frequent highs or high A1c
Lower for frequent lows or frequent lows and highs

Basal/Bolus Balance – about 50% of TDD

Corr Factor = 109/TDD (mmol/L) or 1960/TDD (mg/dl)

Correction Bolus % – if over 9% of TDD, move excess into basals or carb boluses

Average BG – < 160 when checking before & after meals, < 140 when checking mainly before meals

Standard Deviation – Keep less than 1/3 of avg BG

The Actual Pump Practices Study

In the APP Study, we looked retrospectively at over a thousand pump wearers across the U.S. to find out:

- How pumps are actually used and
- What influences success.

APP Study Background

- Data from Deltec Cozmo insulin pumps were down-loaded during a routine software upgrade in 2007
- 396 pumps that had BG values directly entered from an attached CozMonitor Freestyle meter were chosen
- These pumps averaged over 73 days of data and over 300 glucose tests per pump.
- Pumos were divided into thirds by average glucose

Walsh J, Roberts R, Bailey T. Guidelines for Optimal Bolus Calculator Settings in Adults. J Diabetes Sci Technol 5(1): 1711-1717, 2011.

APP Study

- Two types of results
  - Typical behaviors of all pumpers
  - Behaviors and data from third with lowest avg BG
- Basal %, CarbF and CorrF formulas were derived from the third with the lowest avg. BG
- 92.7% of pump wearers used the BC to cover carbs (> 2 meals a day)
- 96.5% used the BC to correct high readings

1. J Walsh, R Roberts, T Bailey: J Diab Science & Technology 2010, Vol 4, #5, Sept 2010

Which Way Do You Adjust Settings?

12.6 Which Way Do You Change Your Pump Settings?			
If you are having:	This is the direction to change your:		
	Basal Rates	Carb Factor	Corr Factor
Frequent lows	↓	↑	↑
Frequent highs	↑	↓	↓

The CarbF and CorrF are inversely related to glucose. That is, when the avg. glucose is high, these factors are lowered, and vice versa.

APP Study – What We Found

Glucose, Insulin and Carb Data				
Group:	All 396 Pumps	Low Third	Mid Third	High Third
Avg. Meter BG	184 mg/10.2 mmol	144 mg/dl (8.0)	181 mg/dl (10.0)	227mg/dl (12.6)
BG Tests/Day	4.38	4.73	4.41	4.01
TDD	49.4	47.9	49.1	51.1
Basal %	47.6%	47.6%	47.2%	47.8%
CarbBolus/Day	4.14	4.07	4.20	4.14
CarbGram/Day	189.9	185.2	196.3	187.9
CarbF	11.4	10.8	12.2	11.2

1. J Walsh, R Roberts, T Bailey: J Diab Science & Technology 2010, Vol 4, #5, Sept 2010

APP Study – Correction Results

Correction Doses				
Group:	All 396 Pumps	Low Third	Mid Third	High Third
Avg. Meter BG	184 mg/10.2 mmol	144 mg/dl (8.0)	181 mg/dl (10.0)	227mg/dl (12.6)
CorrBoluses/d	2.12	1.92	2.10	2.35
CorrBolus U/d	5.59 u	4.18 u	5.57 u	7.03 u
CorrBolus %	11.6%	9.0%	11.6%	14.2%
CorrF	55.7	53.6	61.1	52.5
CorrF x TDD	2160	1960	2360	2330

1. J Walsh, R Roberts, T Bailey: J Diab Science & Technology 2010, Vol 4, #5, Sept 2010

Unexpected APP Study Results

- Between low, medium, and high glucose groups:
  - Basal averaged 48% in each group and had no impact on glucose outcomes
  - No difference in grams of carb eaten, or in the number of carb boluses and correction boluses given per day
  - Glucose tests per day were “significant” but had no meaningful impact on glucose outcomes – the highest third tested their glucose almost as often
  - Infusion set failures and occlusions significantly raised the average glucose
- The third with highest BG used MORE insulin – they either need more insulin OR they need to stop losing it

1. J Walsh, R Roberts, T Bailey: J Diab Science & Technology 2010, Vol 4, #5, Sept 2010

APP Study – What Doses Did Successful Pumpers Use?

2. Optimal Insulin Use
Mean Values For Optimal Doses In Best Control Tertile

Insulin Source	% of TDD	Interquartile Range (%)
Basal	47.8%	39.6% to 54.9%
Carb Boluses	43.1%	35.6% to 51.2%
Corr Boluses	9.0%	6.2% to 11.3%
CorrF Rule Number* = 1960 mg/dl per unit (IQR = 1413 to 2151)		
* CorrF Rule Number = Avg CorrF x Avg TDD		

Insulin use in the third (132 pumps) with the lowest average glucose in APP Study

J Walsh, R Roberts, T Bailey: J Diab Science & Technology 2010, Vol 4, #5, Sept 2010

APP Study – Pump Setting Formulas[1]

Basal = ~ 48% of TDD

CarbF = 5.7 x $\frac{\text{Wt(kg)}}{\text{TDD}}$ or 2.6 x $\frac{\text{Wt(lbs)}}{\text{TDD}}$

Corr. Factor = 110/TDD (mmol/L) or 2000/TDD (mg/dl)

The correction factor is inversely related to TDD and to avg. BG

Or use the Pump Settings Tool at
www.diabetesnet.com/diabetes_tools/pumpsettings/

[1]J Walsh, R Roberts, T Bailey: J Diab Science & Technology 2010, Vol 4, #5, Sept 2010

Bolus Calculator Settings

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The Bolus Calculator

Uses settings and logic to make carb and correction bolus recommendations that will match carbs eaten, safely lower high readings, and minimize insulin stacking

Terms

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- **Bolus Calculator (BC)** – what calculates bolus recommendations
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To Set Up a Bolus Calculator, You Need

- The MAJOR factor that is an accurate TDD – adjusted for frequent lows or highs
- Accurate basals (~50% of TDD) – sound sleep
- An accurate CarbF – postmeal control
- An accurate CorrF – lower highs safely
- A glucose correction target or target range
- An accurate DIA – bolus accuracy, avoid stacking

Concerns about the Bolus Calculator

- Most boluses are given within 4.5 to 5 hours of each other and involve insulin stacking
- The DIA has to be accurate to account for insulin stacking – 4.25 to 6.25 hours
- BCs calculate BOB well (except current U.S. Omnipod)
- BCs dramatically differ in how they subtract BOB to get a bolus recommendation

Adjust the TDD to an Improved TDD (iTDD)

TDD = total daily dose (basal + all boluses)

iTDD = TDD adjusted for frequent lows or for avg. BG or A1c when lows are infrequent

Find the Current TDD in the Pump

TDD = 35.19 u

Basal % is low at 36%

2 grams of carb/day means Bolus Wizard is not being used

Utilities –> Average TDD (10 to 30 days)
Or hit escape button from home screen.

Find the Current TDD in CareLink®

Statistics	5/3 - 5/16	
Avg BG (mmol/L)	12.3 ± 5.0	
BG Readings	86	7.6/day
Readings Above Target	66	77%
Readings Below Target	2	2%
Sensor Avg (mmol/L)	10.3 ± 3.7	
Avg AUC > 7.8 (mmol/L)	2.94	4d 17h
Avg AUC < 3.9 (mmol/L)	0.01	4d 17h
Avg Daily Carbs (g)	101 ± 39	
Carbs/Bolus Insulin (g/U)	6.8	
Avg Total Daily Insulin (U)	35.5 ± 5.5	
Avg Daily Basal (U)	20.8	58%
Avg Daily Bolus (U)	14.8	42%

With an avg BG of 12.3 mmol/L (221 mg/dl), the **TDD** of 35.5 u is too low

Basal % is OK (or slightly high) at 58%

When to Change To an iTDD and Why

1. For **frequent lows**, OR highs and lows WHEN the lows come first, lower the current TDD by 5% to 10%
   - With frequent lows, you cannot tell how much excess TDD there is!
2. For a **high A1c or high avg. BG** on a meter WITH FEW LOWS, raise the TDD, using the iTDD Table
3. This gives the **improved TDD (iTDD)**

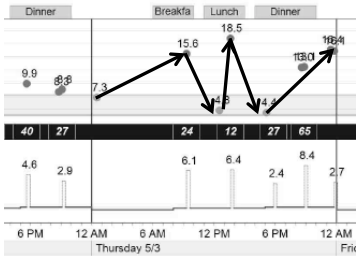
The avg BG for pumps in the APP Study was 10.2 mmol (183.9 mg/dl) –
Most people on a pump need a larger TDD.

For Frequent Lows –

- ***You can't tell how much excess insulin there is!***
- Start with a 5% or 10% reduction in the TDD
- Or:
  - Divide weight(kg) by 1.9, or weight(lb) by 4, to see what TDD they would use if they had a normal sensitivity to insulin
  - Compare the current TDD to this "ideal" TDD for weight.

Example: Someone who weighs 38 kg (84 lbs) would be expected to have a TDD of about 20 units.

What To Do – Reactive Renita



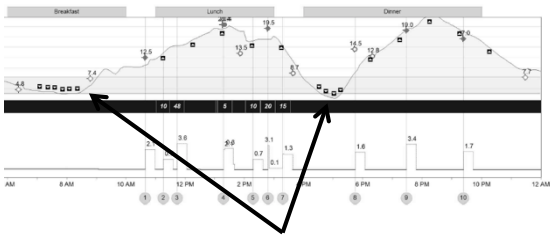
A1c is 6.9%

70 kg/1.9 = 36.8 u/d

Actual TDD = 50.5 u

Speed of drop in glucose suggests she is taking correction dose AND covering carbs in prior meal.

Not All Lows Show Up On a BG Meter



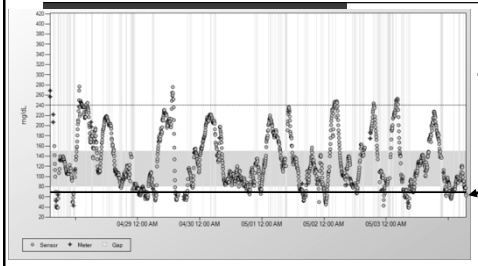
This person felt low and ate, but never tested with a meter. There's no record of these lows without a CGM!

Check for Hidden Lows

People often treat lows from symptoms **BUT DON'T TEST their glucose**

- ☐ Are "other lows" happening?
- ☐ Test when low to record the timing and degree of hypoglycemia
- ☐ Keep a written record of when and how severe these lows are

What To Do?



Frequent lows → lower the average TDD

Clever Pump Trick –
How Many Carbs Do You Need to Treat a Low?

1. 10 grams for each 35 kg or 75 lb of weight
2. PLUS grams = the current BOB* x CarbF

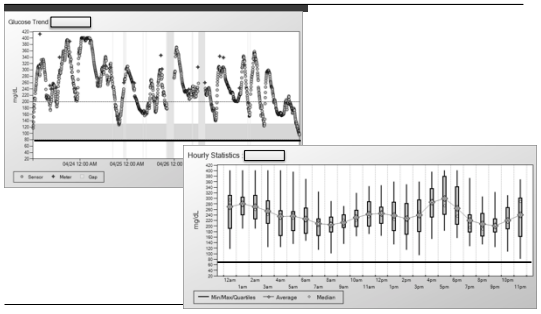
Example:

1. Amy weighs 70 kg (20 grams of carb)
2. And she has 2 units of BOB with a CarbF of 8 grams/unit
   2 u x 8 g/u = 16 grams
3. So, for the low she needs:
   20 g + 16 g = 36 grams

Add extra carbs as needed for recent or planned exercise.

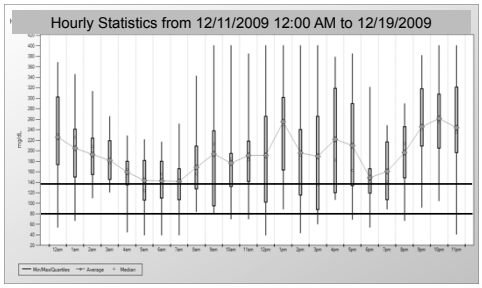
*** To get an accurate BOB, the pump's DIA time setting must be accurate.**

What To Do?



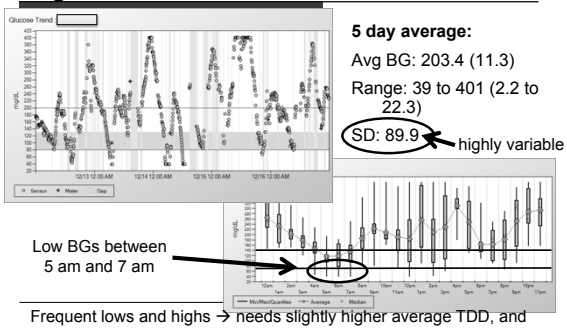
Frequent highs → raise the average TDD

What To Do?



Frequent highs → raise the average TDD

Highs And Lows – But With A Pattern



5 day average:

Avg BG: 203.4 (11.3)

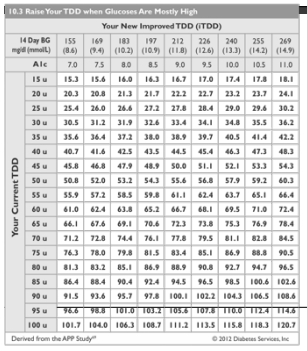
Range: 39 to 401 (2.2 to 22.3)

SD: 89.9 ← highly variable

Low BGs between 5 am and 7 am

Frequent lows and highs → needs slightly higher average TDD, and either a lower night basal or smaller correction boluses at night

The iTDD Table For High Avg. BGs



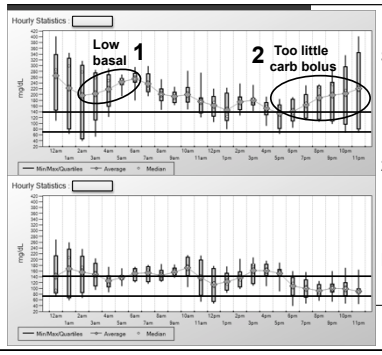
10.3 Raise Your TDD when Glucoses Are Mostly High										
Your New Improved TDD (iTDD)										
14 Day BG mg/dl (mmol/L)		155 (8.6)	169 (9.4)	183 (10.2)	197 (10.9)	212 (11.8)	226 (12.6)	240 (13.3)	255 (14.2)	269 (14.9)
	A1c	7.0	7.5	8.0	8.5	9.0	9.5	10.0	10.5	11.0
Your Current TDD	15 u	15.3	15.6	16.0	16.3	16.7	17.0	17.4	17.8	18.1
	20 u	20.3	20.8	21.3	21.7	22.2	22.7	23.2	23.7	24.1
	25 u	25.4	26.0	26.6	27.2	27.8	28.4	29.0	29.6	30.2
	30 u	30.5	31.2	31.9	32.6	33.4	34.1	34.8	35.5	36.2
	35 u	35.6	36.4	37.2	38.0	38.9	39.7	40.5	41.4	42.2
	40 u	40.7	41.6	42.5	43.5	44.5	45.4	46.3	47.3	48.3
	45 u	45.8	46.8	47.9	48.9	50.0	51.1	52.1	53.3	54.3
	50 u	50.8	52.0	53.2	54.3	55.6	56.8	57.9	59.2	60.3
	55 u	55.9	57.2	58.5	59.8	61.1	62.4	63.7	65.1	66.4
	60 u	61.0	62.4	63.8	65.2	66.7	68.1	69.5	71.0	72.4
	65 u	66.1	67.6	69.1	70.6	72.3	73.8	75.3	76.9	78.4
	70 u	71.2	72.8	74.4	76.1	77.8	79.5	81.1	82.8	84.5
	75 u	76.3	78.0	79.8	81.5	83.4	85.1	86.9	88.8	90.5
	80 u	81.3	83.2	85.1	86.9	88.9	90.8	92.7	94.7	96.5
	85 u	86.4	88.4	90.4	92.4	94.5	96.5	98.5	100.6	102.6
	90 u	91.5	93.6	95.7	97.8	100.1	102.2	104.3	106.5	108.6
	95 u	96.6	98.8	101.0	103.2	105.6	107.8	110.0	112.4	114.6
	100 u	101.7	104.0	106.3	108.7	111.2	113.5	115.8	118.3	120.7

Derived from the APP Study™ © 2012 Diabetes Services, Inc

For frequent highs and few lows, use this table to improve (increase) the current TDD using a meter's 14 day average BG or recent A1c

J Walsh and R Roberts: *Pumping Insulin (5th ed)*, 2012

BGs & TDD before & after Adjustment

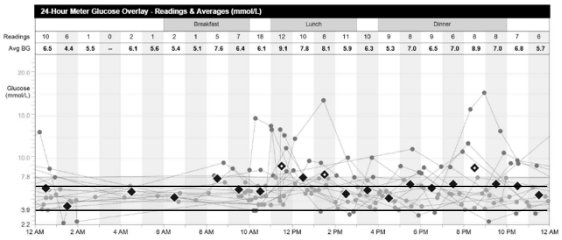


Starting TDD = 36 u

1. Raised basal by 0.05 u/hr all day (+1.2 u/day)
2. Lowered carb factor from 1u/13g to 1u/12g (+1.8 u/day)

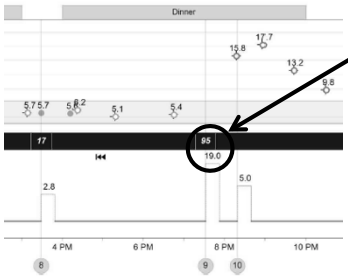
Ending TDD = 39 u

Pregnancy



BGs are relatively flat, but slightly high for pregnancy (red lines). A slightly higher day basal and lower carb factor may help.

Pregnancy



Large carb meals (95 grams) cause post-meal spiking above the target of 120 mg/dl (6.7 mmol/L) or less.

A lower carb factor will not stop this!

Clever Pump Trick – Quick Way to Find an Improved TDD (iTDD)

When the average BG is elevated AND lows are NOT frequent with NO infusion set failures:

For each 0.33 mmol/L (6 mg/dl) you want to lower the average glucose, raise the TDD by 1%

Example: Amy's avg TDD is 40 units/day, her avg BG is 12 mmol/L (216 mg/dl) (infrequent lows), and desired avg BG is 8 mmol/L (144 mg/dl):

12 mmol/L – 8 mmol/L = 4.0 mmol/L

4 mmol/L ÷ 3 = 12, or a 12% rise in TDD

TDD = 40 units x 1.12 = 44.8 units (Amy's new iTDD)

The TDD Must Also Change For:

- ☐ Frequent lows or frequent highs
- ☐ Going on or off a diet
- ☐ Loss or gain of weight
- ☐ Seasonal changes
- ☐ Change in activity or sports
- ☐ Vacation
- ☐ Growth spurts
- ☐ Puberty and menses

Don't wait until the next clinic visit!

APP Study – Importance of the TDD

2. Optimal Insulin Use Mean Values For Optimal Doses In Best Control Tertile		
Insulin Source	**% of TDD**	**Interquartile Range (%)**
Basal	47.8%	39.6% to 54.9%
Carb Boluses	43.1%	35.6% to 51.2%
Corr Boluses	9.0%	6.2% to 11.3%
CorrF Rule Number* = 1960 mg/dl per unit (IQR = 1413 to 2151) * CorrF Rule Number = Avg CorrF x Avg TDD		

Insulin use in the third (132 pumps) with the lowest average glucose in APP Study

J Walsh, R Roberts, T Bailey: J Diab Science & Technology 2010, Vol 4, #5, Sept 2010

Ensure that Pump Settings "Fit the TDD"

9.5 Master List for Bolus Calculator Settings:
Find Your Basal Rates, CarbF, and CorrF from Your TDD (or iTDD) and Weight

TDD or iTDD u/day	Basal [1] u/day	Basal u/hr	Carb Factor [2] in grams/u									CorrF [3] (mg/dl) / u
			100 lbs 45.4 kg	110 lbs 49.9 kg	120 lbs 54.4 kg	130 lbs 60.0 kg	140 lbs 63.5 kg	150 lbs 68.0 kg	160 lbs 72.6 kg	170 lbs 77.1 kg	180 lbs 81.6 kg	
16	7.7	0.32	16.3	17.9	19.5	21.1	22.8					122
20	9.6	0.40	13.0	14.3	15.6	16.9	18.2	19.5	20.8			98.0
24	11.5	0.48	10.8	11.9	13.0	14.1	15.2	16.3	17.3	19.5	21.7	81.7
28	13.4	0.56	9.3	10.2	11.1	12.1	13.0	13.9	14.9	16.7	18.6	70.0
32	15.4	0.64	8.1	8.9	9.8	10.6	11.4	12.2	13.0	14.6	16.3	61.3
36	17.3	0.72	7.2	7.9	8.7	9.4	10.1	10.8	11.6	13.0	14.4	54.4
40	19.2	0.80	6.5	7.2	7.8	8.5	9.1	9.8	10.4	11.7	13.0	49.0
45	21.6	0.90	5.8	6.4	6.9	7.5	8.1	8.7	9.2	10.4	11.6	43.6
50	24.0	1.00	5.2	5.7	6.2	6.8	7.3	7.8	8.3	9.4	10.4	39.2
55	26.4	1.10	4.7	5.2	5.7	6.1	6.6	7.1	7.6	8.5	9.5	35.6
60	28.8	1.20	4.3	4.8	5.2	5.6	6.1	6.5	6.9	7.8	8.7	32.7
65	31.2	1.30	4.0	4.4	4.8	5.2	5.6	6.0	6.4	7.2	8.0	30.2
70	33.6	1.40	3.7	4.1	4.5	4.8	5.2	5.6	5.9	6.7	7.4	28.0
80	38.4	1.60	3.3	3.6	3.9	4.2	4.6	4.9	5.2	5.9	6.5	24.5
90	43.2	1.80	2.9	3.2	3.5	3.8	4.0	4.3	4.6	5.2	5.8	21.8
100	48.0	2.00	2.6	2.9	3.1	3.4	3.6	3.9	4.2	4.7	5.2	19.6

[1] Basal = TDD x 0.48 [2] Carb Factor = 10.8 x insulin sensitivity = (2.6 x Wt (lb))/TDD [3] Correction Factor = 1960/TDD

For exact calculations, use the Pump Setting Tool at opensourcediabetes.org

J Walsh and R Roberts: Pumping Insulin (5th ed), 2012

Basal Rates

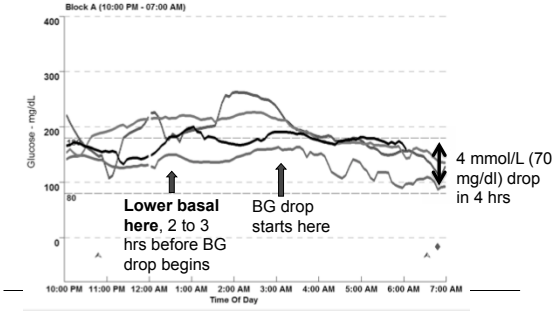
Optimal basal rates keep the glucose flat in a desired range when fasting.

Accurate basal rates are needed before attempting to test and set the CarbF and CorrF.

Raise (or lower) basal rates a couple of hours before the glucose begins to rise (or fall) and 4-8 hours before the high or low glucose you want to avoid.

More than 4-6 basal rates a day usually makes no sense

Overnight Basal Check



Basal/Carb Bolus Balance Is Important

Accurate Basal

50 grams
Bolus = 5u
Basal = 5u
Total = 10u

100 grams
Bolus = 10u
Basal = 5u
Total = 15u

Low Basal

50 grams
Bolus = 7u
Basal = 3u
Total = 10u

100 grams
Bolus = 14u
Basal = 3u
Total = 17u

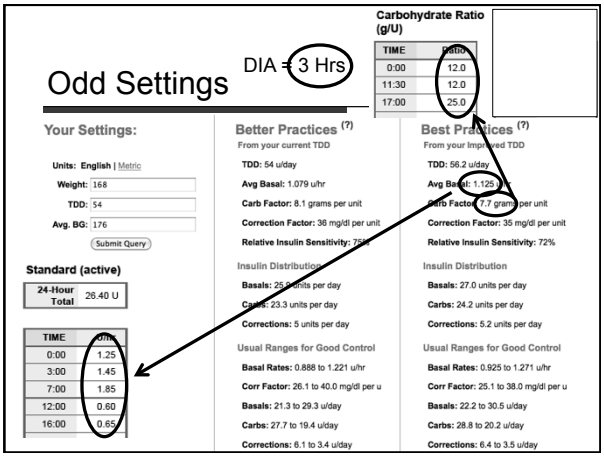
Low basal rates throw the Carb Factor off, causing lows after large carb meals and mild highs after low carb meals. Reverse happens for high basal.

Don't Always Change One Setting!

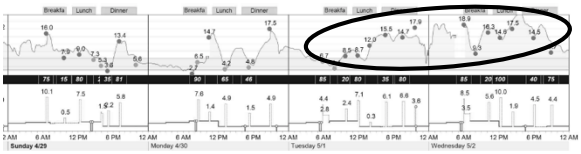
- A pumper may only change the basal rate or only the CarbF (or CorrF or DIA) to fix all control problems
- This can throw the basal/carb bolus balance out of balance
- Periodically check the basal/carb bolus balance!

Odd Settings

DIA = 3 Hrs

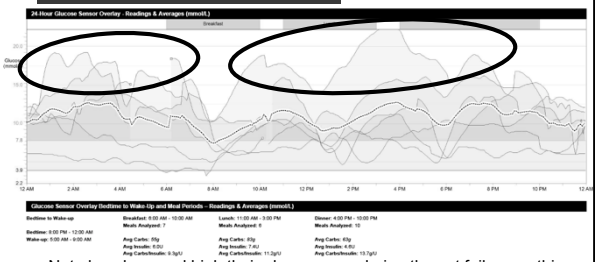


Odd Settings



Unrelated to their odd pump settings, this person also had an infusion set problem that started on the afternoon of May 1st and lasted until late in the day on the 2nd when the infusion set was finally changed.

Odd Settings



Note how long and high their glucose was during the set failure on this CGM tracing

TDD = 54.2 u, Basal = 48%, Avg BG = 9.8 mmol/L +/- 4.8 mmol/L

Clever Pump Trick – Never Stop A Pump!

- It's easy to forget to turn it back on
- It's rarely needed*
- It doesn't help a low glucose

Instead, use a temp basal reduction for 30 to 60 min so pump restarts on time with no followup highs.

To go off a pump for more than an hour, give a bolus to cover most of the missing basal before disconnecting (max time off ~4 hrs).

* Unless hiking 7 mi. out of mountain campsite after bear ate ALL your carbs

Temp Basal Reductions

- At rest, 30% of glucose is consumed by the brain
- More glucose is used during activity – physical or mental
- Temp basal reductions are helpful when a day is physically or mentally active

Carb Factor and Carb Boluses

CarbF = How many mmol/L (or mg/dl) one unit of insulin lowers the glucose.

$$\text{CarbF} = \frac{\text{Wt(kg) x 5.7}}{\text{TDD}} \text{ or } \frac{\text{Wt(lb) x 2.6}}{\text{TDD}}$$

Types of Carb Boluses

Regular

- Taken immediately – for most meals

Combo / dual wave

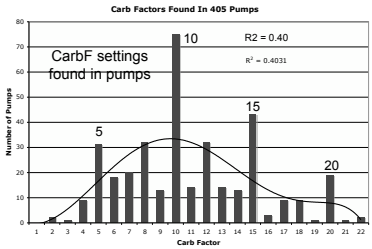
- Some now, some later – bean burrito, some pastas and pizzas, Symlin

Extended / square wave

- Extended over time – gastroparesis

Don't take combo/extended boluses without a clear reason.

APP Study – CarbF Settings In Pumps[1,2]



In APP Study, the carb factors were not evenly distributed.

"Magic" numbers – like 5, 10, 15, and 20 g/unit – are preferred.

Use formulas for settings –> much better than WAG!

Don't use "magic" numbers!

1. J Walsh, R Roberts, T Bailey: J Diab Science & Technology 2010, Vol 4, #5, Sept 2010
2. J. Walsh, D. Wroblewski, and TS Bailey: Insulin Pump Settings – A Major Source For Insulin Dose Errors, Diabetes Technology Meeting 2007

Bolus Overrides – By BC or User?

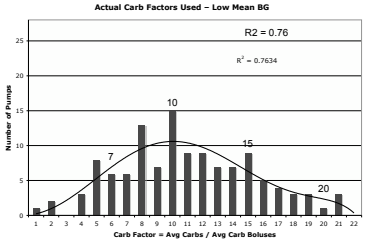
Who Makes Bolus Adjustments?		
	Bolus Calculator	Pump Wearer
Lowered for BOB	1.4 u/day	0.09 u/day
Lowered for Low BG	0.27 u/day	
Raised for High BG	4.18 u/day	0.56 u/day

This pump's bolus calculator* made most of the dose decisions!

HOW it calculates doses IS IMPORTANT!

* Bolus dose adjustments in the lowest glucose tertile.

APP Study – Adjusted CarbFs Used[1,2]



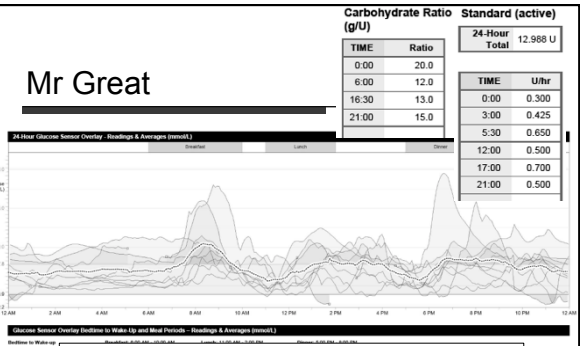
CarbFs actually used – calculated as bolus given for carbs in each meal

– 85% of improvement comes when the BC subtracted BOB from carb boluses or reduced carb boluses for hypoglycemia

Carb Factors actually used in best control tertile – avg carbs/avg carb bolus per meal

1 1. J Walsh, R Roberts, T Bailey: J Diab Science & Technology 2010, Vol 4, #5, Sept 2010
2. J. Walsh, D. Wroblewski, and TS Bailey: Insulin Pump Settings – A Major Source For Insulin Dose Errors, Diabetes Technology Meeting 2007

Mr Great



This person's pump settings are unusual but work. Don't fix!

Avg BG = 7.0 mmol/L (126 mg/dl) +/- 2.8, Basal = 38%, TDD 34.1 u

Small CarbF Changes Have A Big Impact

- Small CarbF changes can make a big difference in the glucose.
- Example: a person weighs 73 kg (160 lbs) and has a TDD of 40 units. A change in CarbF from 1 u/10 grams to 1 u/9 grams will lower the glucose
  - By an extra 1.8 mmol/L (33 mg/dl) for meals with 60 grams of carb, or
  - Or by 3.0 mmol/L (54 mg/dl) for every meal with 100 grams of carb.

CarbF and CorrF Accuracy Is Important

- Don't use "magic" numbers for CarbFs and CorrFs
- Small changes in factors can have a big impact
- Always use formulas to select these settings

How To Get Accurate Boluses

1 Add Carb Bolus to Correction Bolus, then

2 Subtract BOB

3 For an accurate bolus!

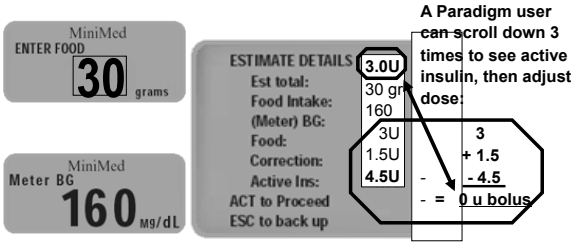
Examples:

1. Carb bolus = 3 u, corr bolus = 1 u, BOB = 4 u
   3 + 1 = 4 4 – 4 = 0 u No bolus needed
2. Carb bolus = 2 u, corr bolus = 1 u, BOB = 4 u
   2 + 1 = 3 3 – 4 = –1 u More carbs are needed

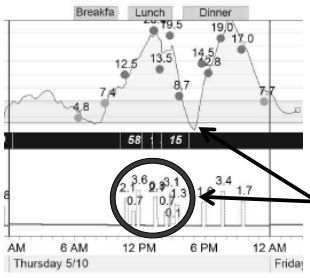
Clever Pump Trick – Quick Way to an Accurate Bolus

1. Is BOB larger or smaller than the correction bolus?
2. If BOB is smaller, pump's recommendation is correct
3. If BOB is larger, subtract BOB from the combined carb and correction boluses

Recommended Bolus Errors Can Be Corrected



Frequent Boluses Cause Stacking

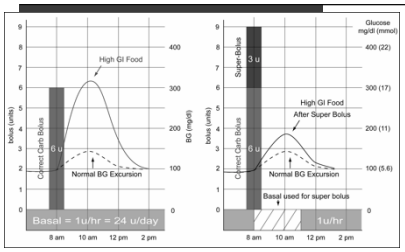


- Patrice waits til her BG is high to give boluses
- This delay causes insulin to stack into the next meal
- Besides, taking 9 boluses over 4 hours creates an **insulin-stacking nightmare**
- No meter test was done that would mark the low

BOB's Blind Spot

- After a carb bolus is given, it takes 90 to 120 minutes to balance the rising glucose from the carbs against the glucose-lowering effect of the carb bolus
- During this time, cover desserts or other carbs with a full carb bolus

Clever Pump Trick – Super Bolus – Shift Basal To Bolus



Helps when eating over 30 to 40 grams of carb

Max carbs/meal = Wt(lb) X 0.36 to stay in control [2]

Future: Super Bolus shifts part of the next 2 to 3.5 hrs of basal insulin into the bolus with less risk of a low later.[1,2]

[1] J. Walsh: http://www.diabetesnet.com/diabetes_presentations/super-bolus.html September, 2004
[2] J. Bondia, E. Dassau, H. Zisser, R. Calm. J. Vehí, L. Jovanovic, F.J. Doyle III, Coordinated basal-bolus for tighter postprandial glucose control in insulin pump therapy, Journal of Diabetes Science and Technology, 3(1), 89-97, 2008

Clever Pump Trick – Measure Insulin Sensitivity

Insulin Sensitivity = $\frac{\text{Wt(kg) x 0.53}}{\text{TDD}}$ or $\frac{\text{Wt(lb) x 0.24}}{\text{TDD}}$

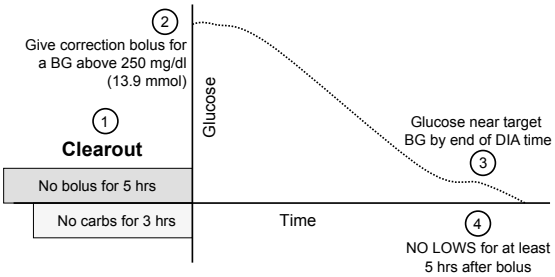
Or use a person's iTDD for even better accuracy!

Or use www.diabetesnet.com/diabetes_tools/pumpsettings/

Correction Boluses

- These make-up doses correct for deficits in basal rates or carb boluses
- Ideally, correction doses make up ≤ 9% of TDD

Test the Correction Factor (and the DIA)



CGM helps check both correction factor and DIA time

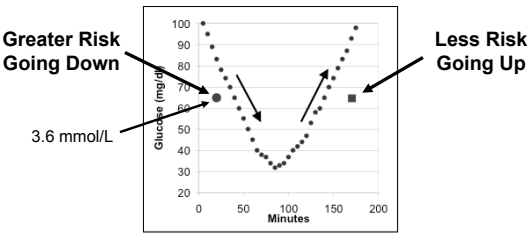
Secrets of the Correction Factor Rule Number

- A 110 Rule (ie, 110 / TDD = CorrF for mmol/L, or 2000 / TDD = CorrF for mg/dl) works well for people in reasonable control
- Lower CarbF rule numbers (80 or 90 for mmol/L or 1500 or 1800 for mg/dl) are better when avg. BG is high due to larger deficits in basal or carb boluses
- Higher rule numbers (120 or 130 for mmol/L or 2200 or 2400 for mg/dl) are better when BGs are well controlled and there are smaller deficits in basal rates and carb boluses

Not All High Readings Are The Same

Cause Of High Reading	Corr. Dose Needed
Jelly on the finger	None (wash, repeat test)
Forgot to bolus	Corr dose **only**
Infusion set failure	Corr + basal replacement
Rebound high after release of stress hormones	Corr + stress coverage .
Ketoacidosis or infection	**Raise TDD)basal and bolus) by 1.5 to 3 fold** + corrections until resolution

Not All BGs Are Created Equal!



Level of a BG's risk depends on its trend

Clever Pump Trick – Fast Correction

To lower a high glucose faster:

- Take usual correction dose
- Add to this a certain amount of carb coverage, say 10 or 20 grams
- Take correction + carb bolus but wait to eat
  - – Lowers glucose faster and pumper knows about how many carbs they'll need to offset the extra BOB!
  - – Eat carbs in time!

Don't use with HU or an aggressive doser

DIA, BOB, & Insulin Stacking

St. Michael's Hospital
Toronto, ON
June 22, 2012

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DIA, BOB, and Insulin Stacking

Duration Of Insulin Action (DIA)
How long a bolus lower the glucose

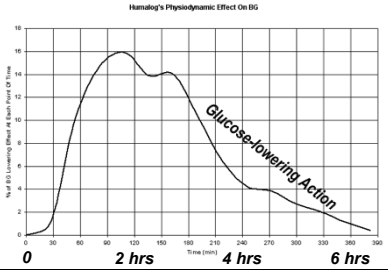
Bolus On Board (BOB)
Bolus insulin still active from recent boluses

Terms

- **TDD** – total daily dose (all basals and boluses) of insulin
- **Basal** –background insulin released slowly through the day
- **Bolus** – a quick release of insulin – Carb boluses cover carbs and Correction boluses lower high readings
- **Bolus Calculator (BC)** – what calculates bolus recommendations
- **Correction Target** – the BG aimed for with correction bolus
- **Bolus On Board (BOB)** – bolus insulin still active from recent boluses, active insulin, insulin on board
- **Duration of Insulin Action (DIA)** – how long a bolus will lower the BG – used to measure BOB

Duration Of Insulin Action (DIA)

*Accurate boluses require an **accurate DIA***



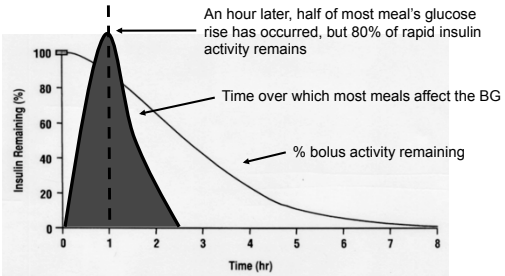
Rapid insulin lowers the glucose for 4.5 to 6.5 hrs.
This DOES NOT CHANGE in the body when DIA time is changed in a pump!

Typical Carb Digestion Times

Food	Digestion Time	Food	Digestion Time
water	0 m	fish	30-60 m
fruit/veg juice	5-20 m	milk/cot cheese	90 m
fruit/veg salad	20-40 m	legumes/beans	2 hr
melons/oranges	30 m	egg	45 m
apples/pears	40 m	chicken	1.5-2 hr
broccoli/caulif	45 m	seeds/nuts	2.5-3 hr
raw carots/beets	50 m	beef/lamb	3-4 hr
potatoes/yams	60 m	cheese	4-5 hr
cornmeal/oats	90 m		

Take Home: Choose combo foods to lengthen carb digestion time

Problem
Most Carbs Are Faster Than "Rapid" Insulin



Take Home: Bolus 15 to 30 minutes before meals
Use extended and combo boluses sparingly

From ***Pumping Insulin***

Clever Pump Trick – Bolus Early To Stop Meal Spiking

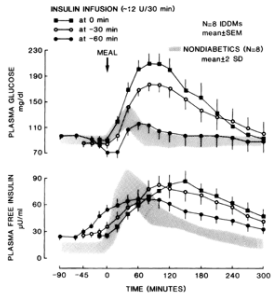


Figure shows rapid insulin injected 0, 30, or 60 min before a meal

Normal glucose and insulin profiles in the shaded areas

Even though, best glucose occurred with 60 minute bolus – **too risky to recommend!!!**

Early boluses – the best-kept secret for better control

A Short DIA Hides Insulin Stacking

3 hours after a 10 unit bolus, this shows how much BOB a pump will think is left with each DIA time:				
	Estimate Of Insulin On Board Remaining			
For a DIA setting =	3 hr	4.5 hr	5.0 hr	5.5 hr
Estimated IOB =	0 u	2.5 u	3.4 u	4.0 u

Always set the DIA from an insulin's real action time

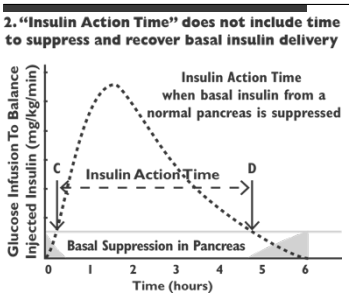
Do not change DIA to fix control problems

Short DIAs Cause Problems

A short DIA hides active BOB and leads to

- Unexplained lows
- Incorrect adjustments in basal rates, carb factors, and correction factors to compensate for excess boluses
- Pump wearer ignoring their "smart" pump's advice

Insulin Action Time From GIR* Studies



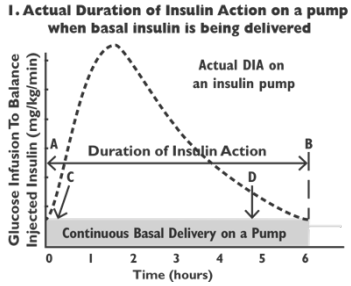
After insulin injection in healthy person, **Insulin Action Time** starts (C) and ends (D) with the IV glucose infusion.

Often quoted as "3 to 5 hours" in insulin handouts.

Glucose infusion (curved line) from C to D does not include the time it takes for injected insulin to suppress or to recover the normal basal insulin output from a healthy pancreas.

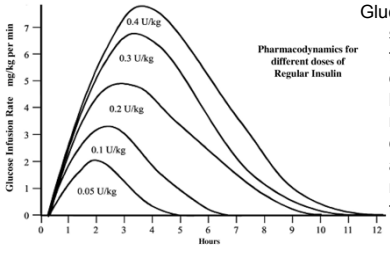
* Glucose infusion rate study

Duration of Insulin Action for Pumps



DIA Time is measured from the time a pump bolus is given (A) to when the bolus insulin action ends (B) **while basal insulin is also delivered from an insulin pump.**

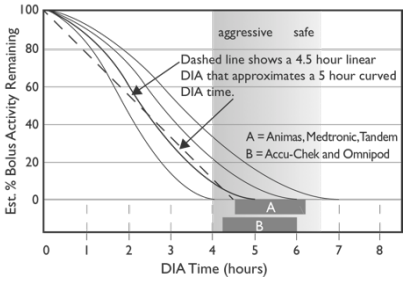
Does Dose Size Really Change DIA?



Glucose infusion rate studies are imprecise themselves. When done in healthy humans, they can make small insulin doses appear faster and insulin appear more variable than they really are.

From: Heinemann L, Woodworth JR: Insulin Lispro; Chapter III: Pharmacokinetics and Metabolism of Insulin Lispro. Drugs of Today 34 (Suppl. C):23-36, 1998

Recommended DIA Times



Set DIA to 4.25 to 6.25 hrs for accurate calculation of BOB and bolus doses

Pumping Insulin, 5th ed., adapted fom Mudaliar et al: Diabetes Care, 22: 1501, 1999

DIA Tips

- Current research suggests that DIA times are NOT different between children and adults
- If the pump does not "give enough bolus insulin", do NOT shorten the DIA to get larger boluses. Look for the real reason:
  - a basal rate that is too low
  - or carb factor that is too high
- Some things do shorten insulin's action time:
  - Increased activity and exercise
  - Hot weather

} ***Don't shorten DIA for these***

Bolus On Board (BOB)[1]

Glucose-lowering activity remaining from recent boluses

An accurate BOB

- *Reduces insulin stacking*
- *Improves bolus accuracy*
- *Reveals current carb or insulin deficit when BG test is done (HypoManager)*
- ***Depends on an accurate DIA***

Basal insulin is NOT included in BOB!

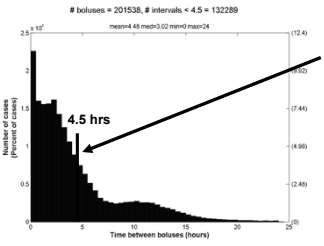
*aka: insulin on board, active insulin, unused insulin**

[1] Introduced as The Unused Insulin Rule in Pumping Insulin, 1st ed, 1989, Chap 12, pgs 70-73

Insulin Stacking

- Happens when 2 or more boluses overlap
- Measured as bolus on board (BOB, IOB, active insulin)
- Used in bolus calculation **IF a glucose is entered**
- **BOB has a Blind Spot** – The impact of a bolus cannot be measured accurately with a glucose test until about 90 to 120 minutes after a bolus is given

BOB Is Present In 65% Of Boluses



APP Study Results

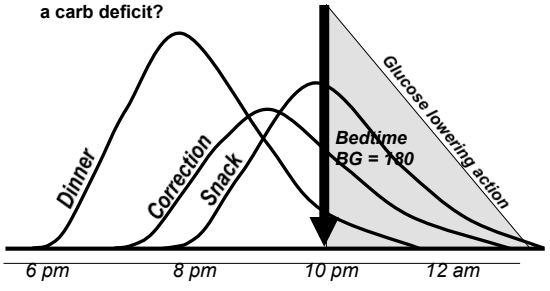
Of 201,538 boluses, 65% were given within 4.5 hrs of a prior bolus

Insulin stacking is common in most boluses taken after breakfast

J. Walsh, D. Wroblewski, and TS Bailey: Disparate Bolus Recommendations In Insulin Pump Therapy. AACE Meeting 2007

Insulin Stacking

Bedtime BG = 10 mmol/L (180 mg/dl) – is there an insulin or a carb deficit?



What Would You Do?

Your daughter's glucose is 6.7 mmol/L (120 mg/dl) at bedtime and she wants a 40 gram snack and has 4 units of BOB.

CarbF = 10 g/u, CorrF = 3 mmol/L (54 mg/dl)
Target = 6.7 mmol/L (120 mg/dl)

Would you:

A. Cover her bedtime carbs with a 4.0 u bolus?

B. Give a smaller bolus for these carbs?

C. Give no carb bolus?

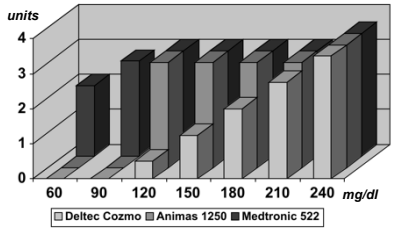
Pumps Differ in How They Handle BOB

What's In BOB & What's It Applied Against?				
	BOB Includes This Bolus		BOB Is Subtracted From This Bolus	
	Carb	Correction	Carb	Correction
Ideal	Yes	Yes	Yes	Yes
Injections	No	No	No	No
Omnipod prior to 2012 in U.S.	No	Yes	No	Yes
Medtronic	Yes	Yes	No	Yes
Animas or Tandem	Yes	Yes	No*	Yes

** Except when BG is below target BG* ***YES = Safer***

Bolus Recommendations Differ

Bolus recommendations differ for same situations.



BOB = 3.0 u and 30 gr. of carb will be eaten at these glucose levels

Carb factor = 1u / 10 gr
Corr. Factor = 1 u / 2.2 mmol over 5.5
Target BG = 5.5
TDD = ~ 50 u

Omnipod bolus cannot be determined - it counts only correction bolus insulin as BOB

Example: Boluses Recommended by 2 Different Pumps on One Morning

How Bolus Recommendations Differ between 2 Pumps						
Time	BG	Carbs Eaten	Carb Bolus	Pump X	Pump Y	Bolus Difference
6:54 am	111 (6.2)	16	0	No bolus		0
9:52 am	174 (9.7)	0	3.0 u *	4.3 u	4.3 u	0
10:35 am	140 (7.8)	50	5.0 u	5.0 u	2.15 u	+ 2.85 u
11:58 am	117 (6.5)	40	4.0 u	4.0 u	0.5 u	+ 3.5 u
1:12 pm	137 (7.6)	0	0	0 u	Eat 19 g	

6.35 more units recommended by Pump X in just 6 hours!

TDD = 38 u, carb factor = 10 g/u, corr factor = 3.6 mmol/L (65 mg/dl)
3.6 mmol/L x 6.35 u = 22.9 mmol (413 mg/dl) fall in BG from Pump X's advice

When to Override a Recommended Bolus

- A pump doesn't know everything – override a bolus recommendation when the situation demands
- Dr. Irl Hirsch suggests that about 25% of all bolus recommendations will be changed when the user knows what they're doing
- Look at the CGM's trend arrow and check the BOB for guidance on overrides

The Correction Target

Where In Correction Target Range Does The Pump Aim?	
Animas	Middle
Medtronic	Top and Bottom
Omnipod	Middle

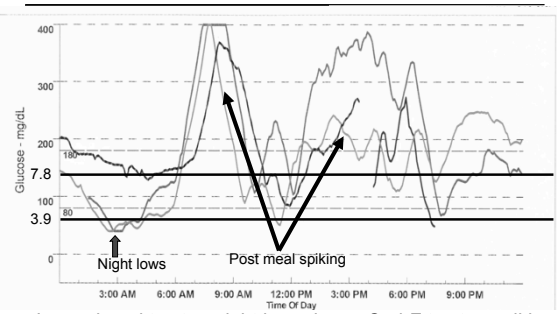
A glucose inside the correction target range will not be corrected.

For a range of 4-10 mmol/L (72 to 180 mg/dl), a BG of 4.1 or 9.9 (73 or 179 mg/dl) is not adjusted for.

Use a single correction target, like 6.1 mmol/L (110 mg/dl), or narrow correction range, like 5.6-6.7 mmol/L (100-120 mg/dl).

*

What To Do



Lower basal to stop night lows, lower CarbF to stop spiking

Clever Pump Trick – Stop Post Meal Spikes

- Count carbs carefully
- Bolus 15 to 30 min before meals if possible
- Use combo bolus (part now/part later) with picky eaters
- When high, wait till below 8 mmol/L (144) before eating
- Eat low GI foods, fewer carbs
- Add fiber/psyllium/acarbose/Symlin/GLP-1 agonist
- Exercise after meals
- Use a Super Bolus

Infusion Set Issues

St. Michael's Hospital
Toronto, ON
June 22, 2012

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(760) 743-1431

View slides at www.diabetesnet.com/presentations/

Terms

- **TDD** – total daily dose (all basals and boluses) of insulin
- **Basal** –background insulin released slowly through the day
- **Bolus** – a quick release of insulin – Carb boluses cover carbs and Correction boluses lower high readings
- **Bolus Calculator (BC)** – what calculates bolus recommendations
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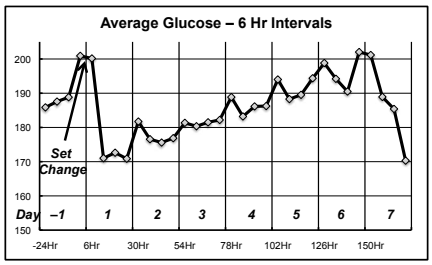
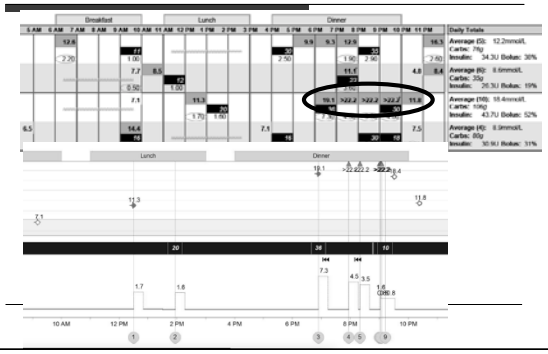
- **Bolus On Board (BOB)** – bolus insulin still active from recent boluses, active insulin, insulin on board
- **Duration of Insulin Action (DIA)** – how long a bolus will lower the BG – used to measure BOB

Glucoses Following A Set Change

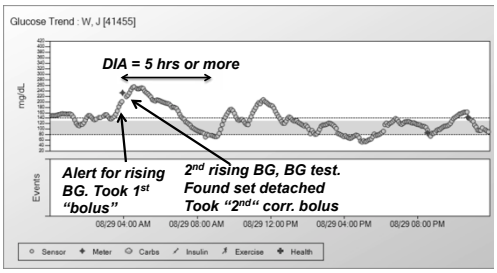


Change in the average glucose during each 6 hr interval following (and just before) the infusion set is changed in 396 insulin pumps.

Infusion Set Failure – Patrice



Infusion Set Failure On CGM



Why Infusion Sets & Patch Pumps Fail:

- Leaking from site (or hub)
- Not taping down the infusion line (tugging)
- Auto-inserters –> bent or kinked Teflon
- Detachment
- Bleeding (hematoma)
- Clogging, blockage, occlusion

Is There an Infusion Set Problem? Ask:

- Do sites often “go bad”?
- Have “scarring” or “poor absorption”?
- Two or more “unexplained” highs in a row?
- Do highs correct when the infusion set is changed?
- Does this happen more than once a year?

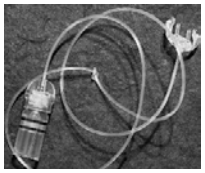
If the answer is yes:

- Anchor the infusion line with tape
- Review site prep technique
- Switch to a different brand of infusion set

APP – Occlusions Worsen Control

BG Tertile	Low	Middle	High
Avg BG	146.6	181.6	229.3
BGs/day	4.74	4.52	4.22
Blocks/ month	1.36	3.04	3.57

Occlusions / Blockages

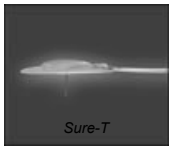


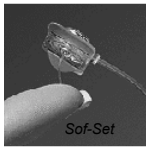
Should not happen!

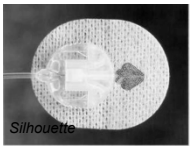
More than once a month?

- *Change infusion set type*
- *Or brand of insulin (rare)*

More Reliable Infusion Sets







ALWAYS anchor the Sof-Set with the *Sof-Set Adhesive Patch*, and the Silhouette infusion line with 1” tape. These steps minimize site irritation and reduce tugging that can cause leaks.

Cost Savings When Budgets Matter

- Most savings come from extended use of sets or sensors
- Risks versus rewards
- Staph carriers are at much higher risk of infection – try to identify these individuals
- Emphasize sterile technique with extended use
- Use lower cost metal infusion sets
- Do not use auto-inserters (close to 10% failure rate)

CGMs For Better Control

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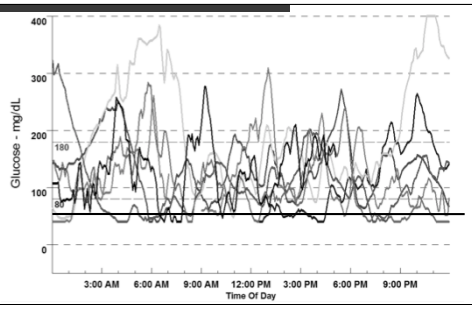
CGM by Jackson Pollack

One Pollack painting sold for $140 million in 1996!

Make Your Own Jackson Pollack



Only $1,000!

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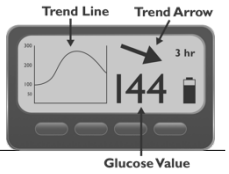
CGM Screen Information

- **Glucose value** – updated every 5 min
- **Trend line** – direction of glucose change
- **Trend arrow** – rate of change: one arrow = 3.3 to 6.7 mmol/L, two arrows = 6.7 to 10 mmol/L
- **Alerts**
  - ☐ High and low thresholds
  - ☐ Prediciton



Where To Set Starting CGM Alerts

LOW: **4.4 mmol/L (80 mg/dl)**

Less than 4.4 in pregnancy

Higher for young children, high risk jobs

HIGH: **11.1 mmol/L (200 mg/dL)** to start

Gradually lower to 10, 8.9, 7.8

The lower the high alert is, the earlier the wearer gets alerted to a rising BG

Adapted from: Hirsch, et al. Clinical Application of Emerging Sensor Technologies in Diabetes Management: Consensus Guidelines for CGM. Diabetes Technology & Therapeutics, 10:4, 2008, 232-244.

Trends And Predictions

- Both help minimize highs and lows
- Good for:
  - Driving
  - Sports
  - Basal tests
  - Reducing uncertainty
  - Overriding bolus recommendations

Picture from Scott Hanselman at http://www.hanselman.com

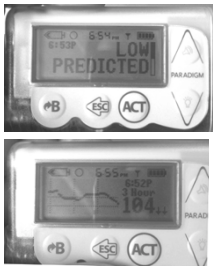
Hypoglycemia Alerts

Hypo or predictive alert, relatively stable BG, and little BOB: mild treatment

- Fewer carbs
- Medium G.I. food

Hypo or predictive alert, dropping BG, + BOB: aggressive treatment

- Full or increased carbs
- High G.I. food



Check BOB for guidance on # of carbs needed!

Pictures from Scott Hanselman at http://www.hanselman.com

Analyze Last Bolus On CGM

Carbs + BG
High, low, or normal

If BG 4-5 hrs later is:	Insulin/Carbs in last 5 hrs:
Too High	Bolus too small
In Target	Bolus in balance
Too Low	Bolus too large

This assumes that the basal rates are appropriate!

CGM Calibration Tips

- Use a **VERY** accurate meter
- Use good technique – clean fingers, no expired strips, enter reading right away
- Follow manufacturer's instructions
- Calibrate up to 4 times a day when the glucose is flat (no arrows)

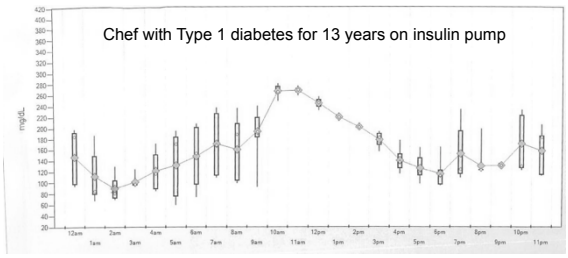
Verify CGM with Fingerstick

- For the first 12 to 24 hours
- When readings differ by 1.7 mmol/L (30 mg/dl) or more
- If CGM readings are erratic or don't seem right
- Before driving
- If CGM remains low 20 or more min. after treating low
- When MAD (mean absolute difference) is above 20%
- Before treating unexplained highs

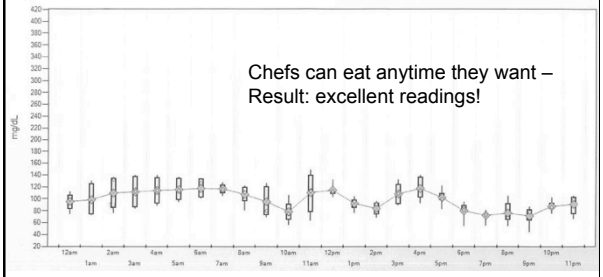
Adjust Boluses For the BG, the Trend, and the BOB

- BG Stable:
  Usual Bolus Dose
- BG Rising Gradually:
  ↑ bolus 10%
- BG Rising Sharply:
  ↑ bolus 20%
- BG Dropping Gradually:
  ↓ bolus 10%
- BG Dropping Sharply:
  ↓ bolus 20%

CGM As Behavior Mod Tool: A Chef's First Two Days On CGM

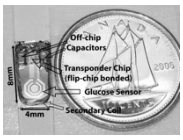


Chef's CGM Next Two Days



An Ideal Pump

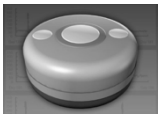
Long-Lasting Implanted CGMs



- *Few disposables*
- *Minor surgery*
- *Funded as rental?*

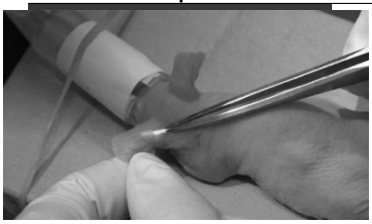
Sensors For Medicine

MicroCHIPS Illume



GlySens

CGM – Implanted Fluorescent



Molecules fluoresce & change color as glucose rises or falls

- Small size, low power, low cost, long life, great accuracy
- Dual fluorescent chambers for low and high BGs

From Y. J. Heo et al: Institute of Industrial Science at the University of Tokyo

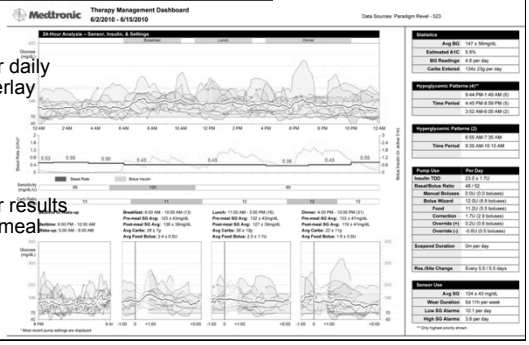
CGM Tips

- Wear the CGM at least 90% of the time
- Look at the monitor 10-20 times per day
- Look at trends not just individual values!
- Don't over-react to data – Avoid frequent between meal corrections until pattern is clear
- A rapid rise usually means more insulin needed, BUT check BOB first!
- Lag times are longest when the glucose is changing direction from down to up or up to down
- Calibrate!

CareLink® 3.0 Online Reports

Sensor daily overlay

Sensor results by meal



Future Pump Features

- Show How A Setting Change Will Impact TDD & BG
- Temp Basal + Bolus Doses
- Super Bolus
- Meal Size Boluses
- Excess BOB Alert (bolusing without BG but ++BOB)
- Low BG Predictor Using Meter (HypoManager)
- Exercise Compensator
- Infusion Set Monitor – Leak Detector
- Automated Bolus and Basal Testing

Still The Best Way To Learn

Slides at www.diabetesnet.com/diabetes-resources/diabetes-presentations
Books at www.diabetesnet.com/dmall/ or 800-988-4772