

The Latest on Pumps and CGMs



Toronto Congress Center
Toronto, ON
June 23, 2012

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Many Thanks

To
Animas Canada,
and especially Richard Forster,
Robin Dales, and Lorraine Anderson

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, Bidel, Dexcom, Novo Nordisk
 - Pump Trainer – Accu-Chek, Animas, Medtronic, Omnipod
 - Web Advertising – Sanofi-Aventis, Sooil, Medtronic, Animas, Accu-Chek, Abbott, etc.
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What We'll Cover

- Actual Pump Practices Study Results
 - Importance of the Total Daily Dose
 - Handling Insulin Stacking
 - Infusion Set Issues
 - CGMs for Better Control
-

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
-

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 downloaded during a routine software upgrade in 2007
- 396 pumps that had BG values directly entered from an attached CozMonitor Freestyle meter were chosen
- An average of over 73 days of data and over 300 glucose tests per pump.
- Pumps 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 396 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

APP Study – BG, Basal & Carb Results

Insulin Use				
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

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%

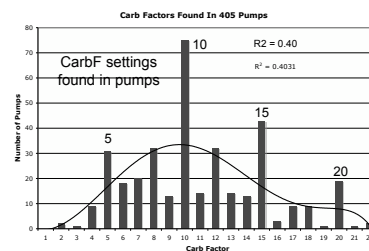
CorrF Rule Number* = 1960 mg/dl per unit (IQR = 1413 to 2151)

*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 – CarbF Settings In Pumps^{1,2}



Carb factors are not evenly distributed.

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

Use formulas for setting accuracy → much better than WAG!

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?

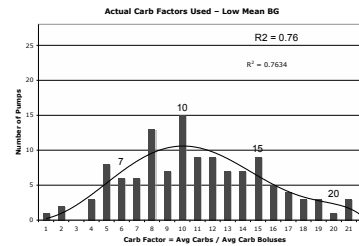
	Bolus Calculator	Pump Wearer
Lowered for BOB	1.4 u/day	0.09 u/day
Lowered for Low BG	0.27 u/day	
Raised for High BG	4.18 u/day	0.56 u/day

The bolus calculator* makes 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 reduces carb doses for BOB and hypoglycemia

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

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

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

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

Select Appropriate Goals

ADA Age-Appropriate A1c And Meter Goals		
Age	A1c	Approx. Avg. Meter Glucose *
Less than 6	7.5% to 8.5%	168 to 197 (180)
6 to 12	8% or less	183 or less (170)
Over 12	7.5% or less	168 or less (160)
Over 19	7% or less	154 or less (150)
AACE: Over 19	6.5% or less	140 or less (140)

Most adults aim for a meter average of 8.6 mmol/L (154 mg/dl) or less

ISPAD goal is ≤ 7.5% for everyone, with few hypos

* With only premeal BGs, meter average would be lower than these values.

Dose For Success



1. Stop lows first
2. Find an iTDD – for 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, Symlin, etc.
6. Set & test CorrF – to bring highs down safely

Enjoy good control or return to #1

Brittle diabetes or frequent highs usually = the wrong settings

To Set Up Your Pump BC Correctly

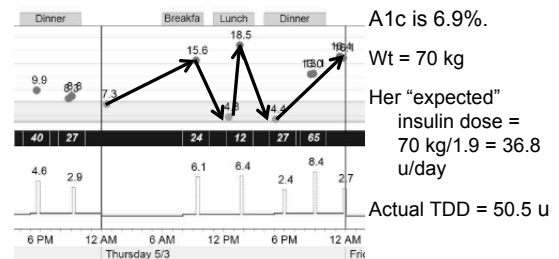
Your health care professional will determine:

- An accurate TDD (MAJOR factor)
- Accurate basals (~50% of TDD)
- An accurate CarbF
- An accurate CorrF
- An accurate DIA (from research studies)

The “Other Things” You Need

- 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
- Don’t over-treat lows with carbs
- Don’t over-treat highs with insulin
- Don’t give blind boluses

What To Do – Reactive Rene



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

Find An iTDD* To Correct Glucose Problems

* improved Total Daily Dose of Insulin

Your TDD

- Controls the average glucose
- Makes it easy to find accurate basal rates, CarbF, and CorrF
- These allow lower and more stable BGs

Use pattern management to fine tune doses & settings

APP Study – Pump Setting Formulas¹

Basal = ~ 48% of TDD

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

Corr. Factor = 110/TDD (mmol/L) or 1960/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 Walsh, R Roberts, T Bailey: J Diab Science & Technology 2010, Vol 4, #5, Sept 2010

Find the iTDD

If current BGs are not great:

1. Lower the current TDD by about 5% for:
 - Frequent lows
 - Or highs AND lows IF lows come first
2. Raise the TDD, using the iTDD Table on next slide to adjust for high A1c or high meter average
 - Increase TDD by 1% for each 0.3 mmol/L drop in avg BG
3. This gives the improved TDD (iTDD)

Keep basal and carb bolus totals balanced

Avg BG on pumps is 183.9 mg/dl (10.2 mmol) – most need larger TDD.

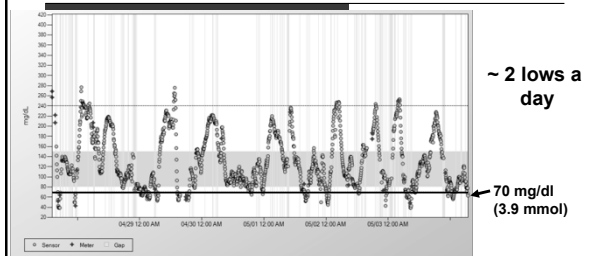
The iTDD Table For High Avg. BGs

10.3 Raise Your TDD when Glucose Are Mostly High		Your New Improved TDD (iTDD)									
14 Day BG (mg/dl)	155	169	183	197	212	226	240	255	269	284	299
A1c	7.0	7.5	8.0	8.5	9.0	9.5	10.0	10.5	11.0		
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	72.2	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		

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

What To Do?



For 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

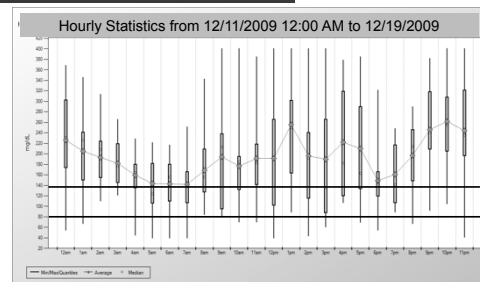
Example:

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

Add extra carbs as needed for recent or planned exercise.

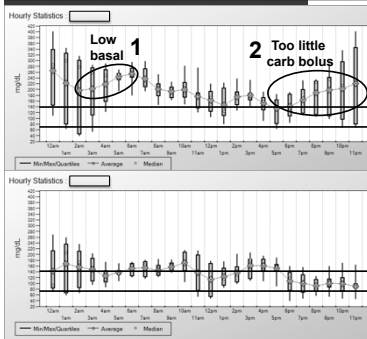
* To get an accurate BOB, the pump's DIA time setting must be accurate.

What To Do?



For frequent highs → raise the average TDD

TDD Before & After Adjustment

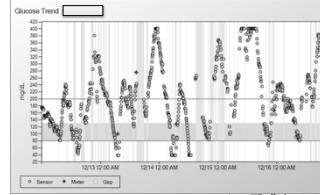


Start TDD = 36 u

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)

End TDD = 39 u

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

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 u/day	Basal u/hr	Carb Factor ¹ in grams/u												CorrF ² (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	190 lbs 86.1 kg	200 lbs 90.7 kg				
14	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 ÷ 0.48 ² Carb Factor = 108 × insulin sensitivity = (2.6 × Wt (kg))/TDD ³ Correction Factor = 1960/TDD
For exact calculations, use the Pump Setting Tool at open-source diabetes.org © 2012 Diabetes Services, Inc. J. Welsh and R. Roberts: Pumping Insulin (5th ed), 2012

Change The TDD 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!

DIA, BOB, and Insulin Stacking

Duration Of Insulin Action (DIA)

How long a bolus lower the glucose

Bolus On Board (BOB)

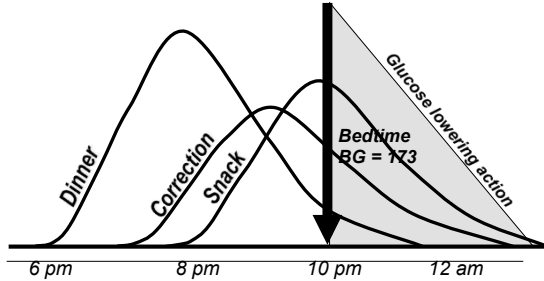
Bolus insulin still active from recent boluses

Insulin Stacking

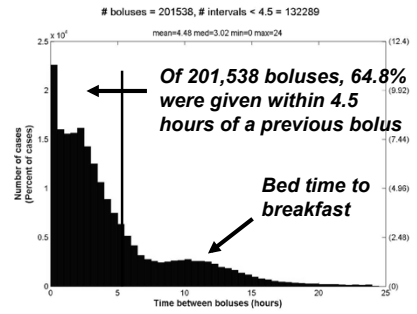
- Happens anytime two or more boluses overlap
- Measured in pump as bolus on board (BOB, IOB, active insulin)
- Used in new bolus calculation **once a glucose is entered**
- Impact of a bolus can't be measured accurately against BG value until 90 to 120 minutes after it was given
- The safest way to minimize insulin stacking is to subtract BOB from correction bolus first, then from a carb bolus if there is BOB remaining

Insulin Stacking

Bedtime BG = 173 mg/dl – is there an insulin or a carb deficit?



Insulin Stacking Is Common



Disparate Bolus on Board Recommendations in Insulin Pump Therapy by J Walsh, D Wroblewski, T Bailey. Poster 2007 AACE Meeting

What Would You Do?

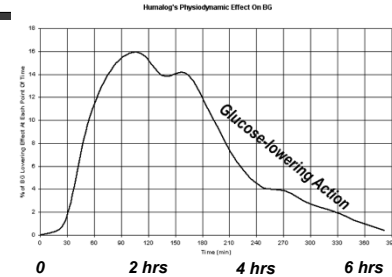
Your daughter's glucose is 6.7 mmol/L (121 mg/dl) at bedtime and she wants a 40 gram snack and has 4 units of BOB.

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

Would you:

- Cover her bedtime carbs with a 4.0 u bolus?
- Give a smaller bolus for these carbs?
- Give no carb bolus?

Duration Of Insulin Action (DIA)



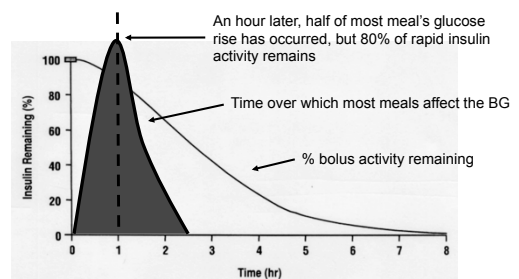
Rapid insulin lowers the glucose for 4.5 to 6.5 hrs.
This is physiologic – it DOES NOT CHANGE in the body when you change the DIA setting in your pump!

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 carrots/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

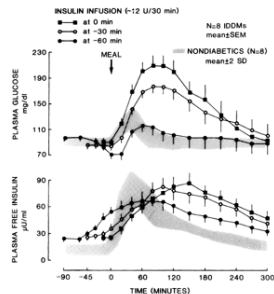


Figure shows rapid insulin injected 0, 30, or 60 min before a meal

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

No Two Pump BCs Give Same Bolus Recommendations

Two hours after dinner when she has 5 u of BOB left, a pump user eats a 50 gram dessert on 4 consecutive nights. Her glucose and the bolus recommendations from different pumps are shown.

Pumps Give Different Bolus Recommendations					
	Glucose	Actual Need	Animas	Medtronic	Omnipod
CarbF = 10	119 mg/dl	0 u	0 u	5 u	5 u
CorrF = 50	121 mg/dl	0 u	5 u	5 u	5 u
Target = 100	200 mg/dl	2 u	5 u	5 u	7 u
DIA = 5 hrs	300 mg/dl	4 u	5 u	5 u	9 u

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

How To Get Accurate Boluses

- 1 Add Carb and Correction Boluses together and
- 2 Subtract BOB
- 3 To get 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 Boluses Can Be Changed

MiniMed ENTER FOOD **30** grams

ESTIMATE DETAILS
 Est total: 30 gr
 Food Intake: 160
 (Meter) BG: 160
 Food: 3U
 Correction: 1.5U
 Active Ins: 4.5U
 ACT to Proceed
 ESC to back up

A Paradigm user can scroll down 3 times to see active insulin, then adjust dose:

3
 + 1.5
 - 4.5
 = 0 u bolus

The Correction Target

Where In Correction Target Range Does The Pump Aim?

Animas	Middle
Medtronic	Top and Bottom
Omnipod	Middle

Any glucose inside a correction target range is not 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.

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).

*

Clever Pump Trick – How Many Carbs for a Low?

- 10 grams for each 35 kg (75 lbs) of weight
- + grams = the current BOB* x CarbF

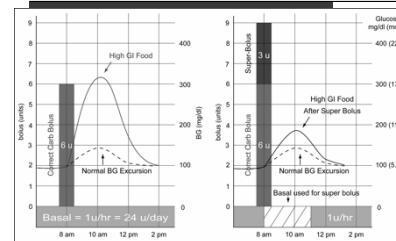
Example:

- Amy weighs 70 kg (150 lbs) = 20 grams of carb
- And she has 2 units of BOB with a CarbF of 8 grams/unit
 $2 \text{ u} \times 8 \text{ g/u} = 16 \text{ grams}$
- For this low she needs:
 $20 \text{ g} + 16 \text{ g} = 36 \text{ grams}$

Add extra carbs as needed for recent or planned exercise.

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

Clever Pump Trick – Super Bolus – Shift Basal To Bolus



Helps when eating over 30 to 40 grams of carb

Max carbs/meal = $\text{Wt}(\text{lb}) \times 0.36$ 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. Vehi, 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

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

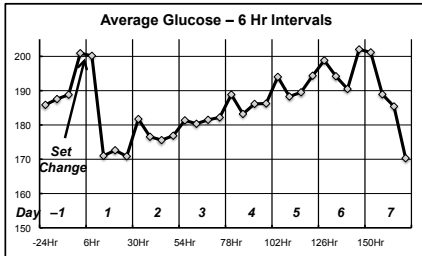
- Extended over time – gastroparesis

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

Infusion Sets

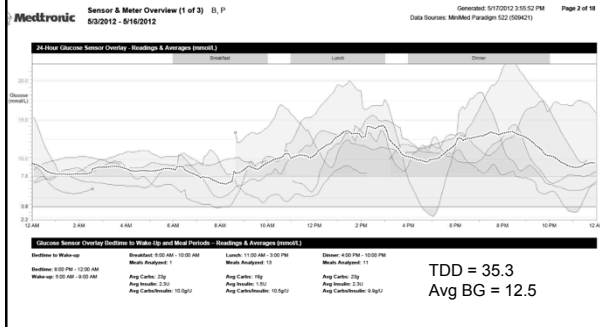
The Achilles Heel of Pumps

Glucoses Following A Set Change

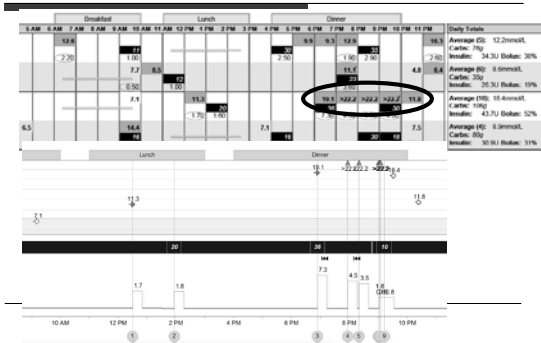


Change in the average glucose during each 6 hr interval following (and just before) the infusion set is changed in 396 insulin pumps.

Infusion Set Failure – Patrice

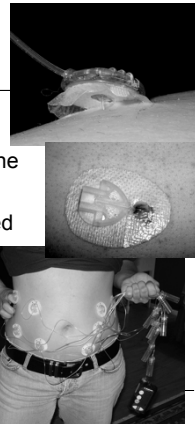


Infusion Set Failure – Patrice



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



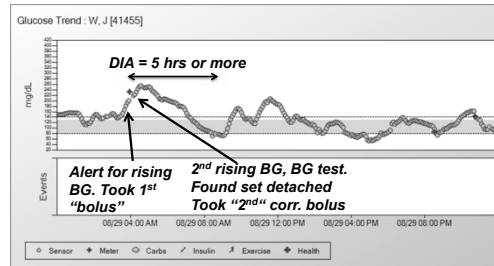
Is There an Infusion Set Problem? Ask:

- 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

Infusion Set Failure On CGM



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

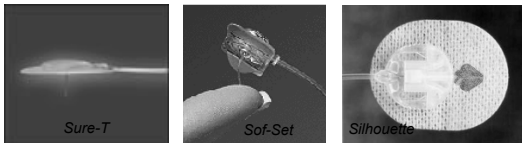
Occlusions / Blockages



*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.

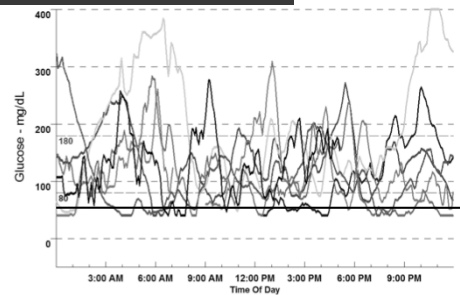
CGMs For Better Control

CGM by Jackson Pollack



One Pollack painting sold for \$140 million in 1996!

Make Your Own Jackson Pollack



Only \$1,000!

CGM Ingredients

Sensor

Receiver

Transmitter

Dexcom sensor on left, Comfort infusion set on right from insulinfactor.com

CGM Benefits

Real-Time

- The way most CGMs are used
- Tracking and trending – fewer extremes
- Shows the direction you're going
- Helps avoid lows, especially night lows
- Avoid foods that spike glucose
- Immediate feedback to change behavior

CGM Systems

DexCom™ SEVEN® PLUS

Medtronic MiniMed Revel® REAL-Time*

CGM Displays

Combines The OmniPod System with Dexcom continuous glucose monitoring system. Your one PDM now is your pump controller, CGM device and BGM device – eliminate the need for carrying 3 different meters / pumps. Upgrade path will be made available once product is approved. Expected filing date in Q1.

dexcom SEVEN PLUS

CGM And Pump Choices

CGM:	Pump:	Available
Dexcom 7+ or Gen 4	Animas	2013
	Insulet	2013
	Tandem	2013
	AccuCheck	2013
Paradigm Rt	Medtronic	now

DexCom™ Seven Plus®

On-Screen Reports

- 1, 3, 6, 12, 24-hr graphs
- Updates every 5 minutes
- Hi/Low alerts
- Rate of Change alerts
- Immediate feedback from screen

Animas Vibe

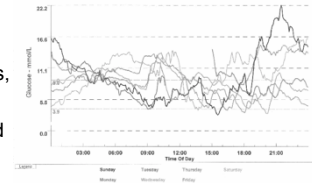


From www.t1diabetes.org/forum/topics/animas-vibe-first-cgmenabled:
 Dude on June 5, 2011 said, "I only just got My Ping, but I would change to this new one in a heartbeat! Please let it come to Canada soon!"
 Mozey on March 26, 2012 said, "I would love to upgrade to this. Govt of Canada dept are slowwwwww to approve, we need a system like Europe for these types of advances.....Siting here waiting"

CGM Benefits

Retrospective View

- See patterns
- Test and tune basals, CarbF, CorrF
- Avoid night lows and hypo unawareness

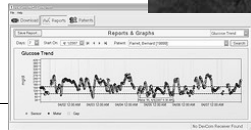


Why Combine Pumps And CGMs?

Precise insulin delivery plus accurate glucose trends. Someone on a pump is more likely to handle 2nd device well.

CGM helps with:

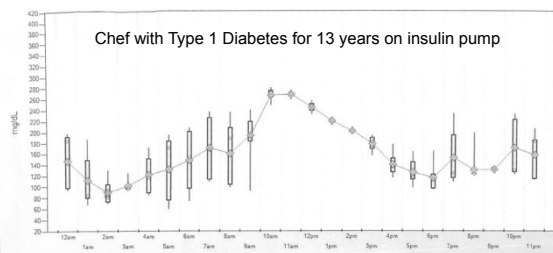
dislodged infusion sets, missed meal boluses, detecting lows, lowering highs, basal and bolus testing, glucose stability, exercise, and stress, overriding bolus recommendations



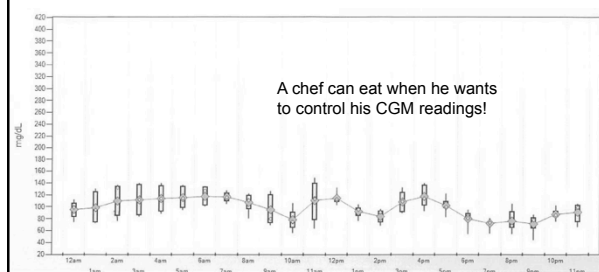
Confidence In Performance



CGM As Behavior Mod Tool: First Two Days On CGM



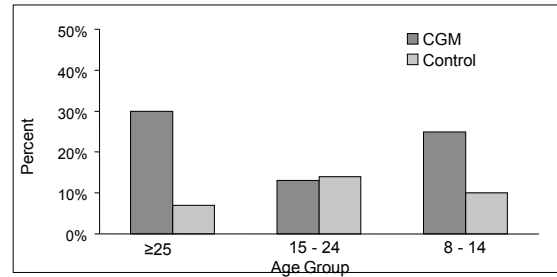
Chef's CGM Next Two Days



Clinical Indications For CGMs

- Frequent hypoglycemia (< 60 mg/dl, 3.3 mmol)
- Hypoglycemia unawareness, pregnancy
- Elevated A1c
- Glycemic variability
- Gastroparesis
- Lives alone
- Presence of complications
- Small children not yet able to recognize and vocalize they are low

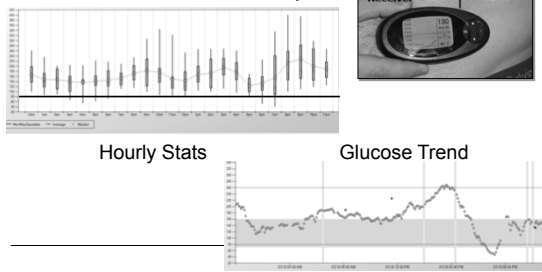
Patients With A1c <7.0 With GCM



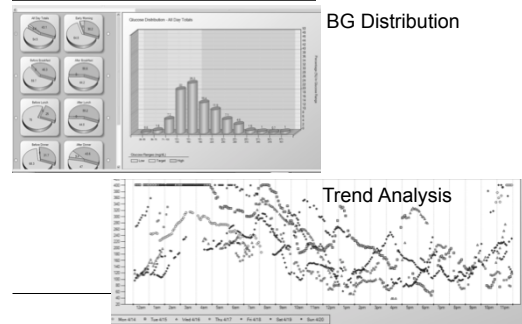
JDRF Continuous Glucose Monitoring Study Group. *N Engl J Med.* 2008;359(14):1464-1476.

DexCom™ 7 STS®

Dexcom DM2 Download Reports



DexCom™ 7 STS®



CGM Benefits

Real-Time

- The way most CGMs are used
- Tracking and trending – fewer extremes
- Avoid lows, especially night lows
- Avoid foods that spike glucose
- Immediate feedback – behavior mod made easy
- Shows direction you're going

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 Show More

Insight



No clue what to do

Photo courtesy Bernard Farrell, www.diabetesdaily.com/farrell/

Consistent Trend Data



Two Dexcom sensors worn by the same person

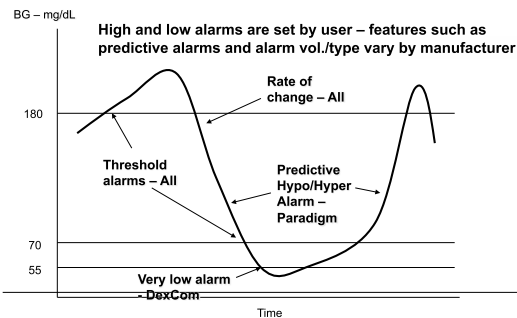
A trend line with ± 1.6 mmol/L accuracy is OK for dosing!

Photo courtesy Bernard Farrell, www.diabetesdaily.com/farrell/

Real Time Data – Off The Screen

- Glucose read every 5 min – 288 readings/day
- Trends
- Rate of change arrows
- Alarms – highs, lows, rate of change, predicted high or low

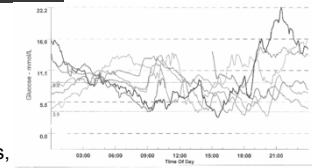
Types Of Alarms



CGM Benefits

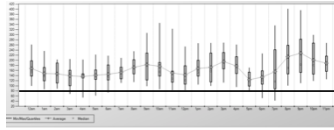
Retrospective View

- NOT used enough
- See patterns
- Test and tune basals, CarbF, CorrF
- Avoid night lows and hypo unawareness
- Peace of mind from fear of lows

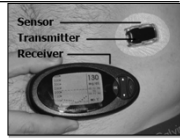


DexCom™ 7 STS®

Dexcom DM2 Download Reports



Hourly Stats

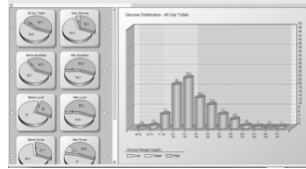


Glucose Trend

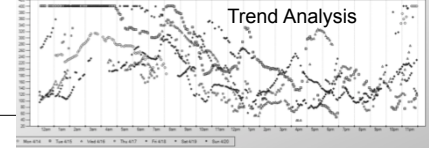


DexCom™ 7 STS®

BG Distribution

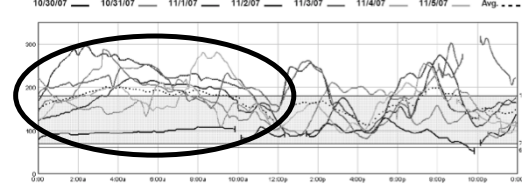


Trend Analysis

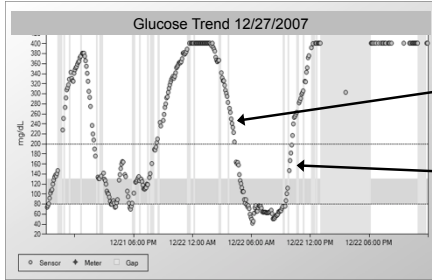


Retrospective Data From Download

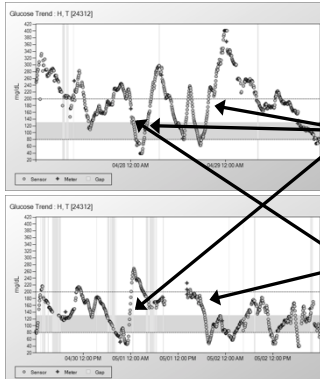
Sensor Data (mg/dL)



Glucose Patterns



High-to-lows
and
Low-to-highs



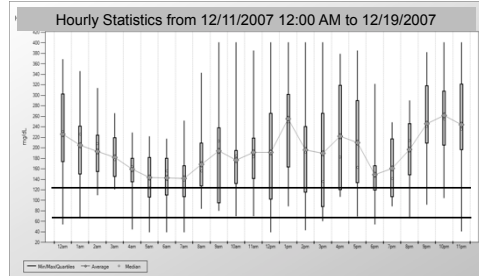
Glucose Trends

Excess low-to-highs

Control improves
by avoiding both

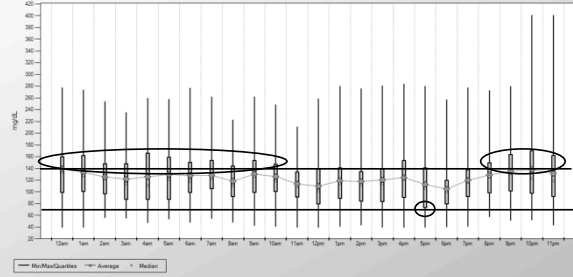
Excess high-to-lows

Hourly Stats Give Insight



Hourly Stats For One Month

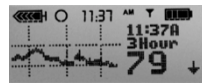
Hourly Statistics from 7/9/2008 12:00 AM to 8/8/2008 12:00 AM



LBL 010399 Rev 01

Verify CGM with Fingerstick

- Before driving
- 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
- If CGM remains low 20 or more min. after treating low
- When MAD (mean absolute difference) is above 20%
- Before treating unexplained highs



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 Dexcom as often as you like, or Medtronic up to 4 times a day when the glucose is flat (no arrows)

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