Future Insulin Pump Features

Ways to improve consistency, ease of use, safety, and medical outcomes with insulin pumps

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Suggestions for improvements and editorial changes are welcome. *Send your approval or comments to: jwalsh@diabetesnet.com or rroberts@diabetesnet.com or call us at (619) 497-0900*

Ver. 12/18/08

Background 1

We have been developing new ideas for several years to make insulin pumps more helpful to wearers. In August, 2008, we began to collect these ideas into PowerPoint slides to distribute as "prior art" to allow their wide use without patentability.

In their current "introductory" form, not all are optimized for ease of use and would have simpler interfaces when integrated into pumps. Many alerts and some tools would operate in the background and be activated only as needed, such as the High Glucose Alert (#22), the Insulin Stacking Alert (#25), and the Infusion Set Monitor (#9).

Background 2

These tools and alerts address issues with current pumps, patch pumps, and infusion sets, but many will be equally useful as continuous monitors integrate with pumps, and as semi-closed and closed loop pumps appear.

Two sections are provided:

- **New Pump Tools (#1 to #21)**
- **New Pump Alerts (#22 to #29)**

More tools and clarifications will be added over the next few weeks at our site http://www.diabetesnet.com/diabetes_presentations/index.php.

Rationale

- Pumps* contain a wealth of underutilized clinical data and have yet to be optimized for their glucose management capability.
- Downloading clinical data for analysis is difficult and often not done, with this lack of analysis greatly limiting their benefits.
- Cell-phone size high resolution color screens and improved memory now allow data analysis and display of results to be done in the pump itself.
- This would speed identification and resolution of glucose control and insulin dosing issues. A clear presentation of these issues inside data currently collected can provide significant medical benefits.

* "Pump" collectively refers to the pump body, PDA, cell phone, or device which controls insulin delivery and stores data.

Overview

These slides present pump tools and alerts that:

1. Maximize benefits from valuable clinical information contained in devices
2. Improve data entry and use, and clarify analyzed data
3. Minimize common errors in pump setting
4. Help identify behaviors and interactions that impact control

Definitions

- **TDD** – total daily dose of insulin (all basals and boluses)
- **Basal** –background insulin pumped slowly through the day to keep BG flat
- **Bolus** – a quick surge of insulin as
  - Carb boluses to cover carbs
  - Correction boluses to lower high readings that arise from too little basal insulin delivery or insufficient carb boluses
- **Bolus On Board (BOB)** – the units of bolus insulin with glucose-lowering activity still working from recent boluses
- **Duration of Insulin Action (DIA)** – time that a bolus will lower the BG. This is used to calculate BOB.

New Pump Tools

1. TDD Adjustor
2. 5 Hour Insulin Analysis
3. Temp Basal & Bolus Doses
4. Multi-step Temp Basals
5. Super Bolus
6. Meal Sizer Bolus
7. Exercise Compensator
8. BG Source ID
9. Infusion Set Monitor
10. Satellite Time
11. Setting Checkers
12. Enhanced Therapy Effectiveness
13. Multi-Linear & Curvilinear DIA
14. Carb Factor Accuracy
15. Automated Carb Factor Testing
16. Correction Factor Accuracy
17. Automated Correction Factor Testing
18. Automated Basal Testing
19. Impact On TDD From New Setting
20. Carb2Cal Estimator
21. BG Manager

1

TDD Adjustor

1

Tool
TDD Adjustor For Highs And Lows

Issue: The average daily TDD is a critical setting to adjust when major control problems occur, but users and clinicians are often confused about when to increase or decrease the TDD to solve control problems

1

Tool
TDD Adjustor For Highs And Lows

Solution: Relate the user's avg. daily TDD to

- The median BG and standard deviation for high readings
- The frequency and timing of lows when lows are the primary problem.

1

Example
TDD Adjustor For Highs

For frequent hyperglycemia or high average BG, pump checks:

- That lows are not frequent or severe

If lows are not frequent or severe, pump checks:

- Basal/carb bolus balance
- Frequency of carb boluses and avg. carb intake for weight
- That basal %, carb factor, and DIA time are appropriate
- Correction bolus %
- Final action: Raise TDD and suggest appropriate adjustments for pump settings

1

Example
TDD Adjustor For Lows

For frequent or severe hypoglycemia, pump checks:

- For specific causes, such as overtreatment of highs, etc
- Basal rate consistency through the day
- Basal/carb bolus balance (The higher value is more likely the cause for the lows)
- Whether lows usually occur before breakfast (lower night basal)
- If usually within 4.5 hrs of carb boluses (raise the carb factor) or a specific meal bolus (raise that correction factor or recheck basal rates)
- If usually within 4.5 hrs of correction boluses (raise the correction factor)

Final action: Suggest use of less insulin (lower TDD) and identify which settings would be most beneficial to adjust (both the direction and degree, given their specific hypo patterns)

Guides
TDD Adjustor

1

How much to adjust the TDD can be estimated from:

- The mean or median glucose
- The relation of daily TDD-to-glucose variability
- Frequency of BGs less than 70 mg/dl *
- Frequency of BGs less than 50 mg/dl (2.7 mmol) *

* Assumes that the glucose is tested during lows

2

Tool
5 Hour Insulin Analysis

Issue: People have difficulty identifying whether basal or bolus insulin is the cause for their high and low glucose readings

2

Tool
5 Hour Insulin Analysis

Solution: Display the quantities of basal, carb bolus, and correction bolus insulin that have been active during the 5 hours prior to a hypoglycemic or hypoglycemia event. This helps identify whether basal or carb or correction boluses are the source for specific high or low glucose readings, and helps the user make appropriate insulin and lifestyle adjustments.

Tool
5 Hr Insulin Analysis

2

When a low or high reading occurs, compare how much:

- **basal,**
- **carb bolus,**
- **and correction bolus insulin**
- was active over the previous 5 hours

When context is considered:

Lows are usually caused by the relatively larger* insulin amount
Highs are usually caused by the smaller insulin* amount

A result is shown for all lows but may want to show for highs only when a “base” BG is available within last 6 hrs or last 8 hrs overnight

* Given that bolus doses are typically larger in daytime and basal doses at night

2

Example: 5 Hr Insulin Analysis

4:19 am BG: 53 mg/dl

In last 5 hours:

Basal	=	4.5 u
Carb boluses	=	0.7 u
Corr. boluses:	=	7.3 u
Carbs	=	0 grams

The insulin imbalance that causes every high or low glucose will not be this obvious but a 5-hr TrackBack over time makes finding the cause more obvious

2

Example: 5 Hr Insulin Analysis

Example # 1

BG = 54 mg/dl (3 mmol) at 1:00 am

Over past 5 hours:

Boluses = 9.2 u

Basal = 4.6 u

Example # 2

BG = 252 mg/dl (14 mmol) at 4:30 pm

Over past 5 hours :

Boluses = 6.5 u

Basal = 2.4 u

Most likely cause

3

Temp Basal And Bolus Doses

3

Tool
Temp Basal And Bolus Doses

Issue: Most circumstances that call for an increase or decrease in the TDD affect both basal rates and carb boluses to the same degree. In circumstances like the following, use of temp basal rates or alternate basal profiles solves only half the problem.

- Exercise or prolonged activity
- Menses
- Stress or pain
- Infection or illness
- Steroid medication
- Dieting
- Vacation
- Nausea

Tool
Temp Basal + Bolus Doses

3

Solution: Let basal rates, carb factors, and correction factors **ALL** be increased or decreased in 5% increments over 1 to 72 hrs and over 3 to 7 days

For example, when a woman adjusts for her menstrual cycle, it is safer to use temp basal plus bolus doses where the return to normal doses is done automatically after a selected period of time than to use an alternate basal profile or alternate insulin profile where the alternate doses must be manually shut off.

Example: temp basal + bolus doses for the next 50 hrs at 125% of normal basals and factors

4

Muti-Step Temp Basals

4

Muti-Step Temp Basals

Issue: In many common situations, it is desirable to use a sequence of more than one temporary basal rate adjustments, such as a short-term reduction for excess BOB that may be present at bedtime, along with an smaller overnight basal reduction after a day of strenuous activity.

Tool
Multi-Step Temp Basals

4

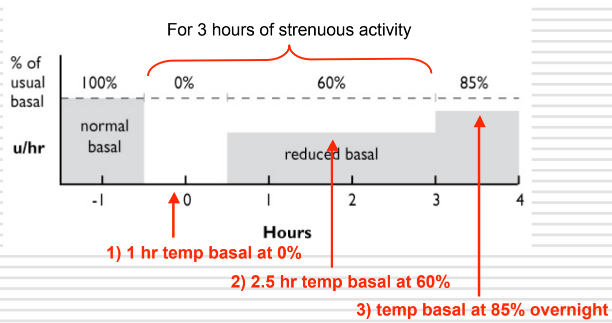
Solution: Having more than a single temp basal can help:

- When someone has excess BOB at bedtime and wants to use a short, large basal reduction to offset BOB rather than eating, they may also need
  - an overnight basal reduction during and after extra activity that day or
  - an overnight basal increase for a high protein (large steak) dinner

Consecutive temp basal rate adjustments would help.

Example
3-Step Temp Basal Reduction

4



5

Super Bolus

Tool
Super Bolus

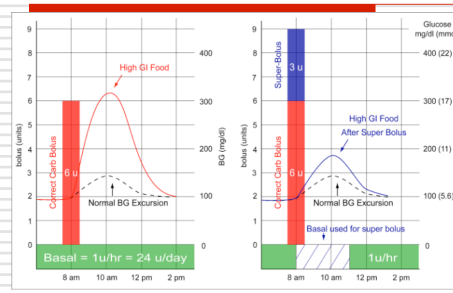
5

Issue: For large carb meals, high GI meals, and faster correction of highs, faster insulin action is desired, but it is difficult to speed up insulin action without increasing insulin. The Super Bolus provides a safe way to speed up insulin action.

First published Sept 9, 2004 as slides 43 through 47 in slide presentation "Changes In Diabetes Care, A History Of Insulin & Pumps – Past, Present, and Future" by John Walsh, P.A., C.D.E., on the web at http://www.childrenwithdiabetes.com/presentations/DMCare-Past-Future-0904_files/v3_document.htm and at http://www.diabetesnet.com/diabetes_technology/DMCare-Past-Future-0904.html.

Tool
Super Bolus For A High GI Meal

5

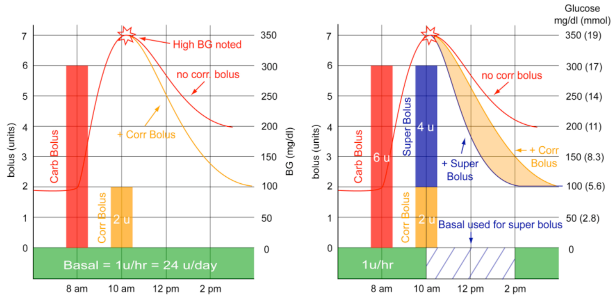


Super Boluses are useful when eating more than 30 or 40 grams of carb, especially for high GI meals like cereal.

A Super Bolus shifts part of the next 2 to 4 hrs of basal insulin into an immediate bolus. This speeds up the action of the insulin for a high GI or a large carb meal with less risk of a low later.

Tool
Super Bolus For A Postmeal High

5



Enables faster but gentler correction of highs with less risk of lows.

6

Meal Size Boluses

Tool
Meal Size Boluses

6

Issue: Pumps currently offer either manual boluses where user determines the bolus need, or carb counting boluses where recommended boluses are automatically adjusted for BOB when a BG is done and carbs counted.

However, some pump users are unable or unwilling to count carbs, but would still benefit from the accuracy of bolus calculations provided by carb counting, rather than relying on mental calculations or guesstimates.

Tool
Meal Size Boluses

6

Solution: As an alternative to carb counting while incorporating its benefit for more accurate bolus calculations, a pump can provide a 1 to 7 or other numbered scale* for various meal sizes that are based on an individualized calorie intake for their weight. The meal size approximates the meal's carb content, and allows the bolus to be adjusted for the current BOB.

* Units of insulin relative to an individual's scale can be determined from their maximum anticipated bolus size (max. grams of carb for a meal for someone of their weight divided by a carb factor determined by 500/TDD).

Example
Meal Size Boluses

6

Table shows how bolus doses vary depending on whether BOB is calculated: carb count vs manual bolus vs meal size (MS = 1 to 7)

		Current		New
		Carb	**Manual**	**Meal Sizer**
Carbs	70 g	7.0u	7.0u	7.0u (MealSize = 5)
BG	100 mg/dl	0.0u	0.0u	0.0u
BOB	1.7 u	–1.7u	0.0 u	-1.7u
Take:		5.3u	7.0u	5.3u

Current bolus options for carb counting versus manual boluses are shown in red box. Meal size boluses on right in green allows those who do not count carbs to account for their BOB.

Tool
Bolus Evaluation

6

- A pump can provide feedback to a wearer who uses either Meal Size Boluses or Carb Counting regarding how appropriate their numerical meal scale or their carb count was for a prior meal based on a glucose result taken 3 to 5 hours later.
- Over time, tracking of post meal glucose results allows the pump to evaluate how appropriate the carb factor or meal size factor has been for that user.
- Over time, pump software can also provide better estimates for the user's carb factor or meal size factors to improve meal bolus accuracy.

7

Exercise Compensator

Tool
Exercise Compensator

7

Issue: Current pumps lack a method to compensate for exercise and activity. This can be a significant issue for maintaining control during and after increased activity.

Tool
Exercise Compensator

7

Solution: ExCarbs, or carb equivalents provide a way to make adjustments for exercise. They can advise an increase in carb intake or a reduction in basal rates or carb bolus, to assist in reducing an elevated glucose, or as a combination of these. These relatively simple calculations in an Exercise Compensator allow the pump to provide exact guidance for handling specific activities.

Review
How The Exercise Compensator Works

7

Inputs:

- Intensity
- Duration
- Training Level
- Weight (occasional)

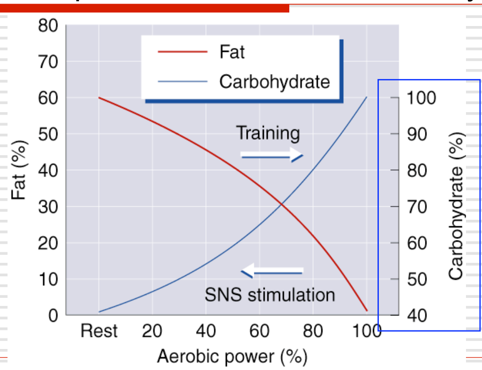
Pump then:

- Translates these inputs into calories or energy equivalents expressed as grams of carb, or ExCarbs[1]
- Uses ExCarbs to determine an appropriate carb increase, carb or correction bolus reduction, basal reduction, reduction of hyperglycemia, or a combination of these for a specific activity.

[1] © Pumping Insulin, 2006, pages 243-264.

Review
Carb Requirement Shifts With Intensity

7



Higher intensity = a higher % of calories from carbs

Review
How Many Calories You Need Is Known

7

EXERCISE & CALORIE GUIDE

ACTIVITY	CALORIES BURNED IN 30 MINUTES 100 LBS.	120 LBS.	140 LBS.	160 LBS.	180 LBS.	200 LBS.	220 LBS.	240 LBS.
AEROBICS (LIGHT)	115	147	173	195	220	246	271	294
AEROBICS (VIGOROUS)	169	203	237	256	290	327	365	400
AEROBICS (WATER)	101	122	142	162	182	203	223	243
BICYCLING (MODERATE - 13MPH)	180	216	252	288	324	360	396	432
GOLF (CARRYING/PULLING CLUBS)	124	149	173	198	223	248	272	297
KARATE/KICK BOXING JUDO/TAE KWAN DO	245	293	342	390	440	490	539	582
RACQUETBALL (COMPETITIVE)	239	279	326	382	419	465	512	570
ROWING (MACHINE/MODERATE)	161	190	223	255	289	326	364	400
RUNNING (12 MIN. MILE)	180	216	252	288	324	360	396	432
RUNNING (10 MIN. MILE)	225	270	315	360	405	450	495	540
RUNNING (8 MIN. MILE)	285	342	395	450	503	559	614	668
STATIONARY CYCLING (MODERATE)	158	189	221	252	284	315	347	378
STATIONARY CYCLING (VIGOROUS)	236	284	331	378	425	473	520	567
SWIMMING (SLOW FREESTYLE)	180	213	247	283	318	354	387	417
SWIMMING (FAST FREESTYLE)	218	263	305	349	393	446	480	528
TENNIS (SINGLES)	180	216	252	288	324	360	396	432
TENNIS (DOUBLES)	135	162	189	216	243	270	297	324
WALKING (SLOW - 2MPH)	61	74	89	101	114	127	140	153
WALKING (MOD. - 3MPH)	91	108	129	143	160	180	196	213
WALKING (FAST - 4MPH)	118	140	161	186	210	235	257	278
WEIGHT TRAINING (CIRCUIT)	180	216	252	288	324	360	396	432
WEIGHT TRAINING (FREE WEIGHTS)	125	150	175	201	225	250	276	300
YOGA	86	105	121	139	156	174	192	209

The calories burned per hour per 100 lbs of weight during an exercise was determined decades ago.

Calories used determined by:

- Weight
- Type and intensity of exercise, such as running at 8 mph
- Duration of activity

Review
Exercise Calories Converted To ExCarbs

7

To determine ExCarbs – number of carbs needed for an exercise, you need to know:

- Calories used in exercise (previous slide)
- The percentage of calories coming from carbs, basically the more intense the exercise, the higher the carb % (approx. 30% at rest to 70% with intense aerobic exercise)
- That basal and bolus doses are accurate without exercise, meaning the BG stays relatively level and normal

Review
ExCarb Formula

7

ExCarbs = $\frac{\text{calories consumed}}{4}$ X % carbs used in exercise for fuel

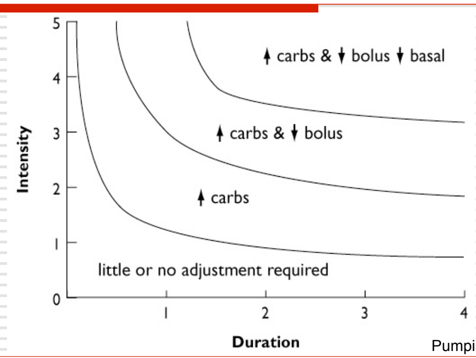
ExCarbs can be consumed as carbs or translated into units of insulin:

$\frac{\text{ExCarbs}}{\text{Carb Factor}}$ = units of insulin

Units of insulin can then be subtracted from carb boluses, correction boluses, or basal rates

Review – Carb Increase & Insulin Reductions Vary With Intensity & Duration

7

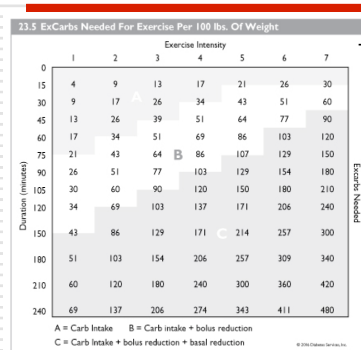


Pumping Insulin, 2009

Both intensity & duration affect carb/insulin changes required for exercise

Review
ExCarbs Per Intensity And Duration

7



23.5 ExCarbs Needed For Exercise Per 100 lbs. Of Weight

Duration (minutes)	Exercise Intensity 1	2	3	4	5	6	7
0							
15	4	9	13	17	21	26	30
30	9	17	26	34	43	51	60
45	13	26	39	51	64	77	90
60	17	34	51	69	86	103	120
75	21	43	64	86	107	129	150
90	26	51	77	103	129	154	180
105	30	60	90	120	150	180	210
120	34	69	103	137	171	206	240
150	43	86	129	171	214	257	300
180	51	103	154	206	257	309	340
210	60	120	180	240	300	360	420
240	69	137	206	274	343	411	480

Excarbs Needed

A = Carb Intake B = Carb intake + bolus reduction
C = Carb Intake + bolus reduction + basal reduction

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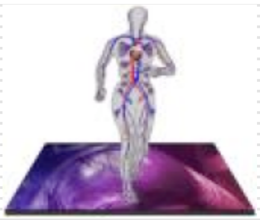
This table from **Pumping Insulin** translates various intensities and durations of aerobic exercise into ExCarbs

Review 7
ExCarbs Can Be Used:



For intake of free carbs,

To lower basal or bolus doses,

To lower a high BG

Or a combination of these

In addition, the pump has the ability to account for any BOB that is present at the start of the exercise.

Example 7
Exercise Compensator Screen 1

My exercise will be

- Intensity: 4* (1-7 scale)
- Duration: 1* hr 20* min
- Starting in: 10* min

My BG: 138 mg/dl**

My training level: 3*** (1-5 scale)

My weight: 187*** lbs

* Adjustable settings in pump/controller
** A glucose test is required to determine correction and BOB
*** Settings that need occasional adjustments

Example 7
Exercise Compensator Screen 2

For intensity “4” lasting 1 hr 20 min, starting in 10 min, BG = 138, and BOB = 1.45 u, you need:

Carbs now*: 22 g**

Carbs after exercise: 20 grams

* Carbs now may be adjusted by user to their preferred intake, with a minimum carb intake set by the pump based on the user’s current BOB and BG.

** Adjustable settings in pump/controller

Example 7
Exercise Compensator Screen 3

Once “carbs now” is selected, the pump determines how to reduce basal or bolus doses.

With 22 grams of carb now, your insulin reduction:

Basal rate: 20% x 1 hr, 80% x 2 hrs, 90% overnight*

Carb bolus: NA

Correction bolus: Accounted for in smaller basal reduction

* Adjustable settings in pump/controller

8

Tool
BG Source ID

8

Tool
BG Source ID

Issue: Are the BG values entered into a pump reliable?

Some users may enter “normal” control or made-up readings to improve the BG average in their pump or to make it appear that they test more frequently. Knowing whether glucose readings are real is critical for appropriate clinical care and decisions.

8

Tool
BG Source ID

Solution:

- Mark each BG entry as (D)irect from meter or (I)ndirect from manual entry
- On a BG summary page, the pump can list the mean BG, median BG, avg. tests per day, SD, and interquartile range for ALL values, DIRECT values, and INDIRECT values (if present) independently.
- BG meter would ideally identify and mark (C)ontrol solution readings as well.

9

Infusion Set Monitor

9

Infusion Set Monitor

Issue: A significant number of pump wearers encounter infusion set problems, but the source for the random and erratic glucose readings that follow is difficult for users and clinicians to identify. These problems may arise from poor infusion set design, selection of an appropriate set, or inadequate site preparation and maintenance. These problems may be less common in patch pumps, but this is not been verified.

9

Infusion Set Monitor

Solution:

1. Insulin pumps shall monitor and record in easily accessible history the duration of infusion set usage recorded as mean, median, and SD of time of use.
2. Insulin pumps shall monitor and report average glucose values in full and partial 24 hour* time intervals between set changes with the ability to change the observation interval, such as 1 to 30 set changes.*
3. These steps allow the pump to identify possible infusion set problems from an increase in the average glucose value over time of use and by variations in length of use.

* Adjustable setting in pump/controller

9

Infusion Set Monitor

Solution (cont.):

3. Insulin pump manuals and training shall improve coverage of specific methods to identify and prevent infusion set failure.
4. Future infusion set designs should incorporate easy to use methods to anchor infusion lines and minimize tugging of the infusion line near an infusion site.

9

Review
Infusion Set Failure

A common infusion set problem arises when a Teflon infusion set comes loose beneath the skin due to movement or tugging. When a space is created between the Teflon and surrounding skin, infused insulin can leak back to the skin surface and cause unexplained high readings.

A complete loss of glucose control can occur when an infusion set pulls out entirely.

Selecting the right infusion set, plus good site technique and taping the infusion line to the skin, significantly reduces loss of control due to these common types of infusion set failure.

Review
Why Tubing Needs To Be Taped

9

Most problems with infusion sets come from loosening of the Teflon under the skin, not from a complete pullout. A 1" tape placed on the infusion line:

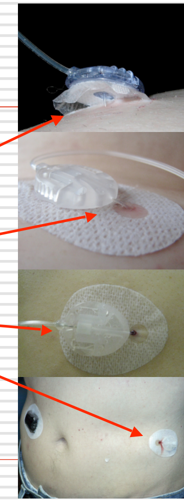
- Stops tugging on the Teflon catheter under the skin
- Prevents loosening of the Teflon catheter under the skin
- Avoids many "unexplained highs" caused when insulin leaks back to the skin surface
- Reduces skin irritation
- And prevents many pull outs

Tape The Tubing

9

This helps prevent

- Tugging
- Irritation
- Bleeding

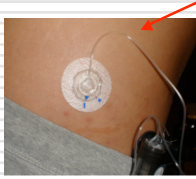


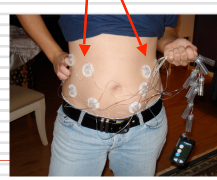
Examples
Lack Of Anchoring Of Sets

9

A review of dozens of pictures of infusion sets online and pump manuals finds that anchoring of the infusion line with tape is rarely recommended or practiced.

No tape!





Review
Need For An Infusion Set Monitor

9

Many pump wearers find that random erratic readings stop when they change to a different infusion set or anchor their infusion lines with tape to stop line tugging.

However, pumps currently have no tool to assist clinicians and pump users in detection of infusion set problems.

Tool
Infusion Set Monitor

9

Insulin pumps with direct BG entry can identify those who may be having intermittent loss of glucose control secondary to infusion set failure. The pump:

- Shows the average time and variation in time of use between reservoir loads or use of the priming function.
- Shows average BGs for each full or partial 24* hour time interval following set changes (indicated by priming of the infusion line) over a preselected number of set changes* or as soon as statistical significance is reached.
- Alerts the user to check their infusion set when an unusual sequence of correction boluses or elevated glucose values occurs.

* Adjustable setting in pump/controller

10

Satellite Time

Tool
Satellite Time For Safety

10

Issue: Pump wearers who travel across time zones currently have to set time on their pump manually.

If a pumper's basal rates vary significantly during the day and they forget to reset time or make an error in setting AM or PM, they will receive too much or too little basal insulin delivery at unexpected times of the day.

Tool
Satellite Time For Safety

10

Solution: Like cell phones and other mobile devices, a pump will automatically correct to a satellite for the correct local time and ask the user whether they wish to adjust their basal rates to the new time. The user may agree or delay this decision until later.

11

Setting Checkers

This section is under development

Tool
Setting Checkers 11

- Pump data already contains TDD, basal and bolus doses, glucose values, carb intakes and frequency, correction bolus doses and frequency, and DIA.
- Entry of age, sex, weight, and activity level can benefit tools such as the Exercise Compensator, basal percentage approximations, etc.
- Pump can then show typical personalized values given these variables and recommend changes identified by comparing current setting to "best practices" settings.

Tools
TDD Checker 11

Compare user's settings to typical ranges as a clinical guide for adjustments

- Evaluate relationship of TDD to avgerage BG, and the frequency, severity, and timing of lows and highs
  - If avg. BG is high with few lows, TDD can be raised
- TDD Variability – Check for TDD excursions over a 14 to 90 day period to identify intermittent control problems, such as from infusion set failures, intermittent pain, stress, etc

Pump checks TDD:

- Against average BG and hypos
- For basal/carb bolus balance – 45 to 60%*
- To Correction Bolus – < 8%*
- Correction Factor to Carb Factor Ratio – 4 to 6*
- DIA time – 4.5 to 6.0 hrs*

Tools
Basal Rate Checker 11

- Basal/carb bolus balance – 45 to 60%*
- Avg day versus avg night basal rates
- Frequency of use of temp basal rates (# per week)
- **Day Vs Night Basal Rates** – Large variation suggests basal issue

Tools
Carb Factor Checker

11

- A large variation in carb factorrs during the day suggests a carb counting problem or that basal rates need testing
- Corr Factor To Carb Factor Ratio that varies greatly suggests one or both factors are off. Carb and correction factors are related if basal rates are accurate
  - Corr : Carb = ~4.5 to 5.0
- Carb & correction factors are directly related to basal % of TDD:
  Higher basal % = generally larger carb & corr factors
  Lower basal % = generally smaller carb & correction factors
- Carb and Corr Factor Errors
  - –avg # of carb & correction boluses per day
  - low carb count for BMI with high BGs
  - TDD, carb bolus, and corr bolus variability

Tools
Correction Factor Checker

11

- **Corr Factor To Carb Factor Ratio** – Ratio that varies greatly suggests one or both factors are off. Carb and correction factors are related if basal rates are accurate:
  - Corr : Carb = ~4.0 to 6.0
- Correction factor rises as control approaches normal:
  - Smaller correction boluses are needed as less correction bolus insulin is being used to compensate for missing basal insulin or carb bolus insulin.
- Carb & correction factors are directly related to basal % of TDD:
  Higher basal % = generally larger carb & corr factors
  Lower basal % = generally smaller carb & correction factors
- Carb and Corr Factor Errors
  - –avg # of carb & correction boluses per day
  - TDD, carb bolus, and corr bolus variability

Tools
Bolus Monitor

11

- Basal/carb bolus balance
- Correction bolus percentage
- Mean, low, and high number of carb and correction boluses per day
  - Along with avg carbs/day, helps identify missed boluses
- What % of boluses are provided though a wizard
  - Is smart pump providing maximum utility
- What % of boluses recommended by wizard are changed by user
  - Do pump settings need to change
- Avg, High, and Low Carbs – Detects diet instability, missed carb boluses
- Avg, High, and Low Corrections – Alert to control issues, infusion set problems, etc.
- Excess In Correction Boluses – Helps quantify how much insulin to shift into preventing highs rather than treating them

12

Enhanced Therapy Effectiveness

This section has some repetition with Section 11.

Sample Enhanced Therapy Effectiveness

12

Pump spots issues and suggests typical remedies for:

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

Basal/Bolus Balance – about 50%* of TDD

Correction Factor = ~ carb factor X 4.5-5.5* (mg/dl) or carb factor / 4 (mmol)

Correction Bolus % – if over 8%* 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 1/2 of avg BG or below 65 mg/dl*

* Adjustable settings in pump/controller

Example Current Therapy Effectiveness Scorecard

12

Screen #1 shows avg. BG, tests/day, and stand. deviation

14 Day Average:		
BG	146 mg/dl	← Overall control [1,2]
Tests	3.5/day	← Testing frequency [1,2]
Std Dev	53 mg/dl	← BG variability – aim for less than 65 mg/dl [1]

Available in current [1]Cozmo and [2]Paradigm pumps

Example Current Therapy Effectivenesss Scorecard

12

Screen #2 shows carbs/day, TDD, and percentage of TDD used for carbs, corrections, and basal delivery

14 Day Average:		
Carbs	206 g	← Boluses taken? Low carb diet? [1,2]
TDD	48.58 u	← Adjust for A1c, lows, etc [1,2]
Meal	38.07%	← Carb bolus % of TDD [1]
Corr	4.95%	← Correction less than 8% of TDD? [1]
Basal	56.98%	← Basal at least 40 to 45% of TDD? [1,2]

Available in current [1]Cozmo and [2]Paradigm pumps

Example Enhanced Therapy Effectiveness

12

George has the following issues:

- Frequent highs*
- Low # of carb boluses/day*
- High # of correction boluses/day*
- Relatively high basal % of TDD*

Pump provides possible solution:

- Missed carb boluses may be an issue
- Recommend giving boluses before all meals
- Use missed bolus alerts to increase TDD and prevent frequent highs
- If on a low carb diet (pump self-checks), basal rate may need to be raised

* Most pumps contain the data to perform these analyses

13

Multi-Linear And Curvilinear DIA

13

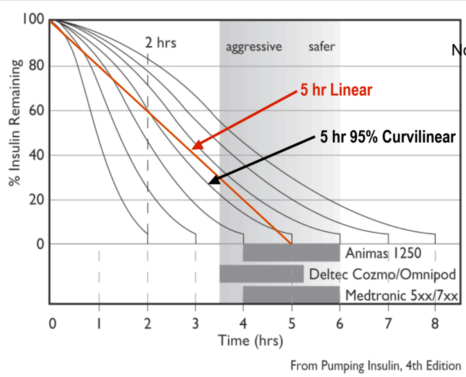
Linear And Curvilinear DIA

Issue: Pump manufacturers use at least 3 different methods (100% curvilinear, 95% of curvilinear, and straight linear) to measure DIA and BOB.

When a realistic DIA time is selected, a linear determination of residual BOB will not be as accurate as a curvilinear method that incorporates the slow onset of insulin action and its longer tailing off in activity. In most situations, an accurate determination of insulin's tailing activity will be most important to the pump user.

13

Linear And Curvilinear DIA Compared



Note how values for the 5 hr linear line in red and the thinner 5 hr curvilinear line diverge in value at several points along the graph.

From *Pumping Insulin*, 4th ed., adapted fom Mudaliar et al: *Diabetes Care*, 22: 1501, 1999

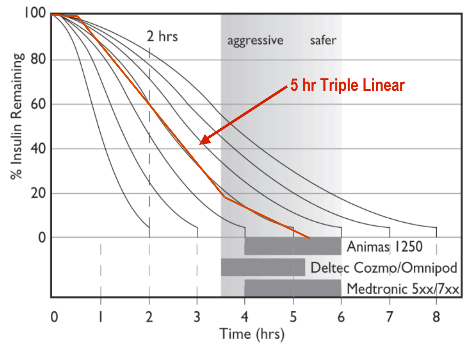
13

Example A Multi-Linear DIA

Use of a multi-linear method to measure DIA improves accuracy. The next page shows a triple-linear example for measurement of BOB.

Example
A Triple-Linear Approximation Of DIA

13



From Pumping Insulin, 4th Edition

A triple-linear line in red can more closely approximate a curvilinear DIA.

For a 5 hr DIA*:

1st 10%** – no change

Mid 65%** – fall 75%**

Last 25%** – fall 25%** (** adjustable as needed in device)

* % modification suggested by Gary Scheiner, MS, CDE

Multi-Linear And Curvilinear DIA

13

Solution: Insulin pumps shall use either a 100% curvilinear or a multi-linear method to improve the accuracy and consistency of BOB estimates.

14

Carb Factor Accuracy

Review
Personal Carb Factor Accuracy

14

Issue: Many carb factors used by people in their insulin pumps today are poorly tuned to the user’s need.

An incorrect carb factor significantly magnifies other sources of error in carb boluses, carb counting, and basal doses.

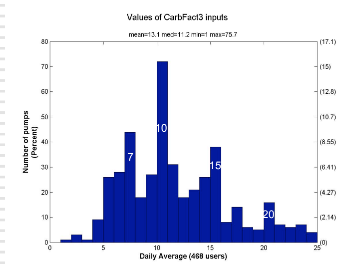
14

Verification Of Carb Factor Accuracy

1. Insulin pump companies are encouraged to record and publish each year the carb factors used in insulin pumps which have been returned for upgrade or repair. This report will include sufficient numbers of pumps to ensure statistical significance for commonly used carb factors, such as between 5 and 20 grams per unit, to ensure that pump training and clinical followup are assisting in the selection of accurate carb factors.
2. To improve accurate selection of carb factors, efforts shall be undertaken to automate carb factor testing.

14

Review
Personal Carb Factors In Use [1]



Avg. carb factors* for 468 consecutive Cozmo insulin pump downloads (>126,000 boluses) are shown in blue.

Note that they are NOT bell-shaped or physiologic.

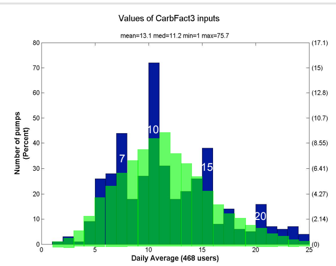
People prefer "magic" numbers – 7, 10, 15, and 20 g/unit – for carb factors and are not deriving their carb factor from a formula that would be more physiologic and accurate.

* Determined directly from grams of carb divided by carb bolus units for each carb bolus

[1] J. Walsh, D. Wroblewski, and TS Bailey: Insulin Pump Settings – A Major Source For Insulin Dose Errors, Diabetes Technology Meeting 2007

14

Review
Personal Carb Factors In Use [1]



MANY magic carb factors, shown in blue, are inaccurate. A more normal or physiologic distribution is shown in green.

Use of magic numbers creates major, consistent bolus errors that magnify other sources for error.

[1] J. Walsh, D. Wroblewski, and TS Bailey: Insulin Pump Settings – A Major Source For Insulin Dose Errors, Diabetes Technology Meeting 2007

14

Review
Deriving Carb Factors From Formulas

Although only indirectly verified from retrospective studies, use of Carb Factor Rule Numbers, such as 450 or 500 divided by the individual's TDD, appear to provide more accurate coverage for meal carbs.

Carb Factor Rule #s = 400 (aggressive) to 600 (safer)

Example:

450/40 u/day = 11 grams per unit as the carb factor

Example
Carb Factor Settings

14

To assist users in setting accurate CarbFs, insulin pumps should allow the user to compare their current CarbF against an optimal settings range of CarbF Rule Numbers. Proposed CarbF Rule Numbers for various TDDs:

Proposed Rule # Ranges For Recommending Carb Factors *		
	Carb Factor Rule Number Range	
Avg. TDD	**More aggressive**	**Less aggressive**
40 u or less	400	500
40 to 80 u	425	600
Over 80 u	500	650

*** Optimal ranges would be determined from research studies of best practices**

14

Carb Factor Setting Accuracy

Solution:

- Encourage use of standard formulas to derive carb factors
- Have pump show the current carb factor(s) compared to an "ideal" one based on formula relative to the TDD
- Assist user to ensure that basal rates are correctly set
- Enable Carb Factor Rule Number Guidance in pumps so users can compare their factor against a standard, such as between 425* (aggressive) to 650* (safer).

15

Automated Carb Factor Testing

15

Automated Carb Factor Testing

Issue: Many pump users don't test their carb factor(s). This leads to consistent errors in carb boluses that then result in incorrect basal rate adjustments, excess use of correction boluses, or user-adjustments of recommended carb boluses.

15

Automated Carb Factor Testing

Solution: Have the pump do automatic carb factor testing:

1. When a premeal BG is relatively normal and BOB is not excessive
2. After subtracting BOB x carb factor from meals bolus, user verifies carb count in meal, then check BGs 2 to 5 hrs after meal with timed reminders and no eating.
3. At end of test, user enter in pump whether they needed to eat to treat a low in last 5 hours

16

Correction Factor Accuracy

16

Personal Correction Factors

Issue: Many correction factors used by people in their insulin pumps today are poorly tuned to the user's need.

An incorrect correction factor significantly magnifies other sources of error in carb boluses and basal rates.

16

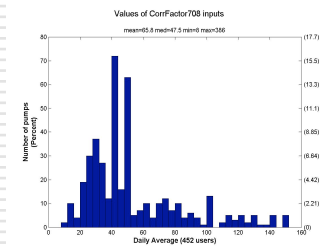
Verification Of Corr Factor Accuracy

1. Insulin pump companies are encouraged to record and publish each year the correction factors used in insulin pumps which have been returned for upgrade or repair. This report will include sufficient numbers of pumps to ensure statistical significance for commonly used correction factors, such as between 20 and 80 mg/dl per unit, to ensure that pump training and clinical followup are assisting in the selection of accurate correction factors.
2. To improve accurate selection of correction factors, efforts shall be undertaken to automate correction factor testing.

Correction Factor Settings

1. To encourage use of consistent and accurate correction factors in pumps, insulin pump companies are encouraged to jointly determine what range of correction factor rule numbers (CorrF x TDD) provides optimal glucose results for various TDD amounts, and that these be published as a reference for users and clinicians.
2. Insulin pump companies are encouraged to voluntarily measure and publish each year the correction factors in use for 200 consecutive downloads from pumps that use correction factors.
3. Monitor correction factors within each pump for accuracy and effectiveness with a report available to users or clinicians.

Review
Personal Correction Factors In Use [1]



- Avg. correction factors in use for 452 consecutive Cozmo insulin pump downloads
- Like carb factors, correction factors in use are NOT bell-shaped or physiologic. A more accurate choice of correction factors would create a bell-shaped curve.
- Users or clinicians frequently select "magic" numbers for correction factors.

[1] J. Walsh, D. Wroblewski, and TS Bailey: Insulin Pump Settings – A Major Source For Insulin Dose Errors, Diabetes Technology Meeting 2007

Review
Deriving Corr Factors From Formulas

Although only indirectly verified from retrospective studies, use of Correction Factor Rule Numbers, such as 1800 or 2000 divided by the individual's TDD, appear to provide more accurate coverage for lowering high glucose readings.

Corr Factor Rule #s = 1700 (aggressive) to 2200 (safer)

Example:

1800/40 u/day = 45 mg/dl per unit as the corr. factor

Example
Correction Factor Settings

To assist users in setting accurate CorrFs, insulin pumps should allow the user to compare their current CorrF against an optimal settings range of CorrF Rule Numbers. Proposed CorrF Rule Numbers for various TDDs:

Proposed Rule # Ranges For Recommending Corr. Factors*		
	Correction Factor Rule Number Range	
Avg. TDD	**More aggressive**	**Less aggressive**
40 u or less	1700	2000
40 to 80 u	1800	2200
Over 80 u	1800	2400

*** Optimal ranges would be determined from research studies of best practices**

Tool
Correction Factor Guide

16

Issue: Many correction factors are poorly tuned/ inaccurate

Tool
Correction Factor Guide

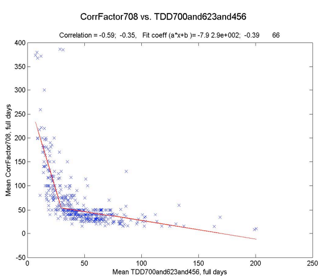
16

Solution: Enable Correction Factor Rule Number Guidance in pump so user can compare their factor against a standard using 1700 (aggressive) to 2400 (safer).

- Encourage use of standard formulas to derive carb factors
- Show user how their current carb factor(s) compare to an "ideal" one based on formula
- Assist user to ensure that basal rates are correctly set

Review
Correction Factor Vs TDD

16



Estimates from the CDA Study suggest Correction Factor Rule Numbers lie between 1500 and 2200, similar to those recommended in Pumping Insulin for different basal percentages of the TDD

As control improves, the Correction Factor Rule Number generally needs to rise because correction boluses are no longer compensating for missing basal or carb bolus insulin.

17

Automated Correction Factor Testing

17

Automated Correction Factor Testing

Issue: Many pump users don't test their correction factor(s). This leads to consistent errors in correction boluses that then result in incorrect basal rate adjustments, or user-adjustments of recommended correction boluses.

17

Automated Correction Factor Testing

Solution: Do automatic correction factor testing:

1. When a BG is elevated (over 200 mg/dl), BOB is not excessive, and no carb bolus is planned for the next 5 hours
2. Have the user give the recommended correction bolus after subtracting any BOB
3. Alert user to check BG 2, 3.5, and 5 hrs later, or sooner if the fall in glucose appears unusually steep.
4. After 3 tests, divide the total fall in glucose by the total correction boluses given to derive a preliminary correction factor
5. Request periodic confirmation tests, especially following a change in basal rates.

18

Automated Basal Testing

18

Automated Basal Testing

Issue: Many pump users don't test their basal rate(s). This leads to consistent errors in basal delivery that result in errors in calculations for carb boluses and correction boluses, and results in suboptimal glucose control.

18

Automated Basal Testing

Solution: Do automatic basal rate testing

18

Example
Automated Basal Testing

Have the pump do an overnight basal test:

1. Measure BOB at bedtime (DIA of 5 hrs for calculation) to estimate expected fall in glucose from BOB (BOB times correction factor)
2. After subtracting BOB x carb factor from bedtime reading, check how flat BG remains overnight with middle of the night BG check or a continuous monitor
3. In AM, the fall or rise in BG plus difference from target BG divided by correction factor equals basal insulin deficit or excess
4. Determine if basal rate is correct. If not, recommend change and test again

19

Impact On TDD From New Setting

19

Tool
Impact On TDD From New Setting

Issue: When user changes a carb factor, a correction factor, their basal rates, the duration of insulin action, or uses a temp basal rate, they may not realize how this change affects their TDD nor how it will affect their glucose results.

Tool
Impact On TDD From New Setting

19

Solution: When a dose setting is adjusted or temp/alternate basal is used, quantify how the setting change affects the TDD (units of insulin taken a day) and how the change in insulin dose is likely to change their glucose results.

Part of this check is to relate the new estimated TDD to the user's current average BG

Example
Impact On TDD From Carb Factor Change

19

A person who averages 190 g of carb/day decides to lower their carb factor from 1u/10g to 1u/9.5g to reduce postmeal highs:

$$\frac{\text{avg carb/day}}{\text{new carb factor}} - \frac{\text{avg carb/day}}{\text{old carb factor}} = \pm \_\_\_\_ \text{ u/day}$$

$$\frac{190 \text{ g/day}}{9.5 \text{ g/u}} - \frac{190 \text{ g/day}}{10 \text{ g/u}}$$

(20.0 u/day) – (19.0 u/day) = **+ 1 u/day**

+ 1 u/day of carb bolus = ~17 mg/dl lower BG/meal *

(correction factor = 50 mg/dl)

* The effect of a carb factor change on BG can be quantified for typical carb intake for each period of the day.

20

Carb2Cal Estimator

Tool
Carb2Cal Estimator

20

Issue: Many parents of kids, users, and clinicians are unable to tell whether the daily average grams of carb listed in the pump's history screen represents an appropriate carb intake for this person or whether they may be undercounting carbs or missing some carb boluses.

Tool
Carb2Cal Estimator

20

Solution: People are generally more aware of appropriate calorie intakes per day than carb intakes. Convert avg. grams of carb per day into avg. calories per day, assuming that 40% to 50% of calories* will be carbs (adapt for low or high carb diets).

Avg carbs/day X 10 = calories/day for a 40% carb diet

Avg carbs/day X 8 = calories/day for a 50% carb diet

* Adjustable settings in pump/controller

BG Manager

21

Tools
BG Manager

21

Opportunity: The current HypoManger (Cosmo pump) or history screen (other pumps) can be expanded beyond treatment of highs and lows to provide information on their causes and adjustments to make to improve control.

Review
HypoManager

21

Current Cozmo HypoManager shows current insulin OR carb deficit. This feature:

- Corrects high readings (similar to other pumps)
- Recommends a carb intake that is appropriate for that situation to help reduce overeating when BG is low
- Warns when carbs may be needed later even though current BG is OK or high (The poor man's continuous monitor)

How it works – BOB is compared to correction bolus need:

- When BOB is smaller –> pump recommends **a correction bolus**
- When BOB is larger –> pump recommends **eating carbs**

Tool
BG Manager

21

A Blood Glucose Manager:

- Expands the HypoManager concept
- Like the HypoManager, identifies corrective action needed now or later for excess or inadequate BOB
- Also serves as a learning tool:
  - When BG goes high, it estimates the excess in uncovered carbs that created the high
  - When BG goes low, it estimates the insulin excess that created the low

Tool
BG Manager For Highs

21

- For a high glucose, pump suggests:

> "Take ___ u now ?
> In the last 5 hrs, you needed
> an extra ___ u *
> or ___ g fewer carbs."

or for a high BG after a meal when enough BOB is present:

> "Your bolus dose appears
> adequate (enough BOB),
> did you bolus early enough?"

* carb bolus or basal insulin (after accounting for BOB)

Tool
BG Manager For Lows

21

- For a low glucose, pump suggests:

> "Eat ___ grams now.
> In the last 5 hrs, you had
> about ___u excess insulin*."
>
> carb bolus or basal insulin
> (after accounting for BOB)

New Pump Alerts

22. Too Many Lows
23. Too Many Highs
24. Too Many Lows And Highs
25. Excess Correction Boluses Alert
26. Insulin Stacking Alert
27. Meal Delay Reminder
28. Bolus Override Monitor
29. Unusual Highs

22

Too Many Lows Or Highs

22

Too Many Lows Or Highs

Issue: Although most current insulin pumps contain sufficient data to determine when a user is experiencing patterns of frequent or severe low or high readings, no presentation of glucose patterns is offered and no warning is given when dangerous patterns appear.

22

Too Many Lows

1. Presentation of a pump user's glucose control data in a clear and readily accessible form on the pump assists improvements in control.
2. The user should also be alerted when their glucose data suggests they are experiencing frequent* or severe* patterns of hypoglycemia.

* Adjustable settings in pump/controller

22

Example
Pump Screen Hypoglycemia Display 1

To improve statistics for a better understanding of the severity and frequency of low glucose events over time (weeks), the pump can provide a screen such as the following:

Weekly History – Low BGs				
# of weeks	1	2	4	8
# BGs/week	23	25	28	32
% BGs/week < 50 mg/dl*	22%	18%	11%	8%
% BGs/week < 70 mg/dl*	35%	27%	19%	16%

* Modified to % display per Gary Scheiner, MS, CDE

* Adjustable settings in pump/controller

Example
Pump Screen Hypoglycemia Display 2

22

The daily timing for severity and frequency of hypoglycemia can be shown in a screen such as the following:

Low BGs By Time Of Day	For 1 Week*			
Avg BGs for 1 week	23 (3.3/day)			
Time Period	4a-10a	10a-4p	4a-10p	10p-4a
# and % BGs < 50 mg/dl*	4 (57%)	1 (14%)	0 (0%)	0 (0%)
# and % BGs < 70 mg/dl*	5 (71%)	2 (28%)	0 (0%)	1 (14%)

* Modified to % display per Gary Scheiner, MS, CDE

* Adjustable settings in pump/controller

Too Many Lows Alert

22

Solution: Depending on the settings selected by the user and clinician, an alert would sound when a pattern of hypoglycemia events exceeds a pre-selected threshold for frequency* or severity* of hypoglycemia.

Additionally, typical ways to resolve particular glucose patterns occurring at this time can be viewed.

* Adjustable settings in pump/controller

23

Too Many Highs

Too Many Highs

23

1. Presentation of a pump user's glucose control data in a clear and readily accessible form on the pump assists improvements in control.
2. The user should also be alerted when their glucose data suggests they are experiencing frequent* or severe* patterns of hyperglycemia.

* Adjustable settings in pump/controller

Example
Pump Screen Hyperglycemia Display 1

23

To improve statistics for a better understanding of the severity and frequency of high glucose events over time (weeks), the pump can provide a screen such as the following:

Weekly History – High BGs				
# of weeks	1	2	4	8
Avg BGs/week	23	25	28	32
% BGs/wk > 180 mg/dl*	26%	30%	29%	26%
% BGs/wk >220 mg/dl*	17%	18%	22%	23%

* Modified to % display per Gary Scheiner, MS, CDE

* Adjustable settings in pump/controller

Example
Pump Screen Hyperglycemia Display 2

23

The daily timing for severity and frequency of hyperglycemia can be shown in a screen such as the following:

Low BGs By Time Of Day	For 4 Weeks*			
# BGs for 4 weeks	112 (4.0/day)			
Time Period	4a-10a	10a-4p	4a-10p	10p-4a
# and % BGs > 180 mg/dl*	1 (1%)	3 (3%)	4 (4%)	22 (21%)
# and % BGs > 220 mg/dl*	0 (0%)	2 (2%)	3 (3%)	18%

* Modified to % display per Gary Scheiner, MS, CDE

* Adjustable settings in pump/controller

23

Too Many Highs

Solution: Depending on the settings selected by the user and clinician, an alert would sound when a pattern of hyperglycemia events exceeds a pre-selected threshold for frequency* or severity* of hyperglycemia.

Additionally, typical ways to resolve particular glucose patterns occurring at this time can be viewed.

* Adjustable settings in pump/controller

24

Too Many Lows And Highs

Too Many Lows And Highs

Issue: When a pattern of frequent high and low readings occur (excessive variability), they are usually related:

1. A pattern of lows may make a pump user afraid to give adequate carb boluses or lead them to excessively lower basal rates
2. Overtreatment of lows may be followed by giving excessive correction boluses
3. A correction factor is too small and leads to correction boluses that are too large

Too Many Lows And Highs

Solution: When lows and highs are frequent, the lows must be stopped first. This usually requires a reduction in insulin doses. With sufficient glucose testing (4 or more tests per day), the pump can determine likely causes for various patterns of glucose variability.

Use of the Settings Checked can be helpful here.

* Adjustable settings in pump/controller

Example
Too Many Lows And Highs

* Adjustable settings in pump/controller

Excess Correction Boluses Alert

25

Excess Correction Boluses Alert

Issue: When glucose levels consistently run high, many pump users address the problem by giving frequent correction boluses rather than correcting the core problem through an increase in their basal rates or carb boluses.

If the correction bolus % becomes excessive relative to the TDD, a pump often does not show this information, and no alert is given regarding the possible excessive use of correction boluses.

25

Excess Correction Boluses Alert

Solution: Alert the user (and HCP) when their correction boluses become excessive and show the percentage of the TDD used for correction boluses in a clear and readily accessible history screen.

The pump wearer should also be alerted by their pump when they use more than a pre-selected percentage (such as 8%*) of their TDD as correction bolus doses over a pre-selected time interval (such as a 3 day* period).

If lows are not a major cause for highs, show the user the average number of units per day in excess of their pre-selected percentage of TDD so the excess can be added to basal rates or carb boluses.

* Adjustable settings in pump/controller

25

Excess Correction Boluses Alert

When correction boluses become excessive and lows are NOT a problem:

- Move at least half of any excess units above 8%* into basal rates or carb boluses
  - Raise the basal rates
  - Lower the carb factor
  - Or stop skipping carb boluses – A comparison of the average number of carbs eaten per day and the average number of carb boluses per day can help detect bolus skipping

* Adjustable setting in pump/controller

25

Example
Correction Boluses Over 8%*

10 Day Average:

Carbs	175 g
TDD	54.1 u
Meal	36%
Corr	21% ← **Over 8%***
Basal	43%

54 yo, 184 lb. male with Type 1 DM and rare hypoglycemia

Move 1/2 of the overage to basals or carb boluses:

- 21% of 54.1 = 11.3 units, 8% of 54.1 = 4.3 units
- 11.3 u - 4.3 u = 7 units excess
- 1/3 to 1/2 of 7 u = 2.3 to 3.5 u to add to basals or carb boluses

* Adjustable setting in pump/controller

26

Insulin Stacking Alert

Accurate accounting of BOB is more important for those who are experiencing frequent or severe hypoglycemia, and for those whose average glucose levels are close to normal values.

26

Insulin Stacking Alert

Issue: Pump users often bolus for carbs without checking their glucose first. With no glucose reading, current pumps do not account for BOB, nor warn that a significant quantity of BOB is present when a bolus is planned.

Though no glucose test is done, BOB data in the pump can be used to warn the user that there is sufficient insulin stacking to substantially change their planned bolus dose.

26

Insulin Stacking Alert

When a pump user plans to give a bolus but no glucose value has been entered in the pump, any current insulin stacking* is ignored by the pump and no warning is given. If they were made aware of the insulin stacking, they might significantly alter the bolus they would otherwise give.

The insulin stacking alert would be turned on by default once a DIA time is selected, but may be turned off if the user desires.

* Such as when the BOB is greater than 1.25%** of the avg. TDD, sufficient to change the glucose about 25 mg/dl. (** Adjustable setting in pump/controller for a certain fall in glucose selected by the user or clinician)

26

Example
Insulin Stacking or BOB Alert

When a carb bolus is planned without a recent BG check, but BOB is more than 1.25%* of the average TDD (enough to cause about a 25 mg/dl drop in the glucose), the pump will recommend that the wearer do a BG check due to the substantial presence of BOB.

For instance, for someone with:

Avg TDD	1.25%* of TDD
40 units	0.5 units

50 mg/dl per u (corr factor) X 0.5 u = 25 mg/dl

This individual would be alerted when they do not check their glucose and want to give a bolus but have 0.5 u or more of BOB present.

* Adjustable in pump/controller to provide a reasonable degree of safety

27

Meal Delay Reminder

27

Meal Delay Reminder

Issue: When the glucose is high at mealtime and eating can be delayed, a pump user may want to take a combined carb and correction bolus, and then delay eating until the glucose comes down to a more desired level. However, they do not want to delay too long and experience hypoglycemia.

27

Meal Delay Reminder

Solution: Provide a simple timer that is activated when a high premeal glucose occurs, and alarms after a chosen time period to recheck the glucose prior to eating.

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Bolus Override Monitor

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Bolus And Basal Override Monitor

Issue: Some pump users frequently override their pump's bolus recommendations, rather than correcting the underlying problem in basal rates, carb factor, correction factor, or DIA.

Other users wil make use of frequent temp basal rates to correct an underlying problem in their basal rates.

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Bolus Override Monitor

Solution: The pump can monitor how often and in which direction overrides occur and:

- Alert the user or HCP when more than a pre-selected percentage* (such as 12%) of carb or correction boluses are changed by the user and show the direction and time of day for typical bolus overrides.
- Alert the user and HCP when temp basal rates are used too often and show the direction and timing for use of typical temp basal rates.

* Adjustable setting in pump/controller

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Unusual Highs

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Unusual Highs

Issue: Unusual high glucose readings may be caused by a prolonged deficit of insulin, such as from a loss of basal and bolus delivery due to a displaced infusion set.

In this setting, many users enter the glucose into their pump to obtain a recommended correction bolus and proceed to give the bolus without considering that they may have an insulin delivery problem and that a larger bolus then normal may be required in this situation to lower the high reading, replace missing basal insulin, or overcome extra insulin resistance of ketosis and glucose toxicity.

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Unusual Highs

Solution: An Unusual High Alert warns that a larger than normal correction bolus may be needed for loss of prior basal delivery, possible presence of ketosis, and an extended period of glucose toxicity.

The user should be alerted that their infusion set should be checked and replaced.