Pumps and Dosing Software: The Latest Advances

Andrea Gasper, MS, PA-C



Insulin Pump Options

- Animas 2020
- Accu-Chek Spirit
- Paradigm 522/722
- Deltec Cozmo 1800
- OmniPod









Model 522

"Smart" Pumps

 Meal and/ or correction boluses are calculated based on preprogrammed insulin to carbohydrate ratios, correction factors, glucose targets and insulin duration of action.

Animas 2020 Insulin Pump



- Released 3/19/2007
- The first and only insulin pump with a flat panel, high-contrast color screen.

IR 2020 vs. IR 1250



- Makes for easier viewing and readability
- White-on-dark type and a yellow bar that highlights each function as you navigate the screen.





- Smallest full-feature insulin pump (3" x 2" x .76")
- Smallest basal rate increment (0.025 U/hr)
- Waterproof at 12 feet for 24 hours
- ezCarb: meal bolus calculator w/ optional correction bolus
- ezBG: correction bolus calculator
- ezBolus: shortcut to give set insulin dose

Animas

Carb Counter

Take the guesswork out of counting carbs

- Create a food database on your pump using CalorieKing
- Choose up to 500 foods from a list of 7,000
- · Add family favorites
- Enter up to 9 food items for any one meal – the IR 1250 totals the carbs and calculates the insulin dose



- In-pump food database that can be accessed via the ezCarb bolus menu.
- Select amount of carb based on serving size.
- Total carb number transferred directly to meal bolus calculator.

Direct Glucose Transfer?

- Currently Animas does not offer a meter with direct BG transfer from meter to pump.
- Integrated LifeScan meter is in the works (OneTouch2, OneTouch Ultra).
- Meter will transmit BG wirelessly and it will transmit boluses remotely.



Software for Palm and PC

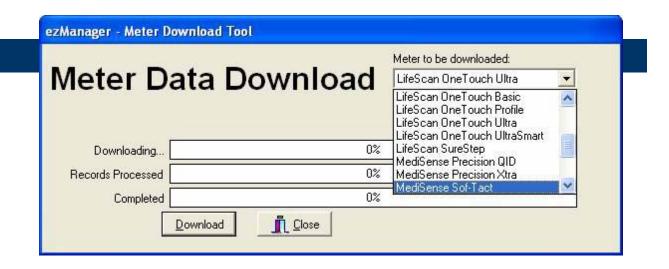






- InfraRed data exchange (IR kit included)
- Download pump settings, manually entered BG values and daily totals from pump to PC (a Mac version will be out later in the year).
- Personalize basal profiles ex. "Weekend" and "School Day"
- Upload music and special tones from a selected list for customized reminders and alerts
- Add sick day quick reference tips

Meters Compatible with ezManager Software



- Most meters with USB adapters will currently upload BG values into the ezManager (Bayer, LifeScan, MediSence, Therasense and Roche) not BD
- BG values will be populated into the insulin delivery reports for the appropriate date and time.

Log Book



Log Book for: Annie Maas

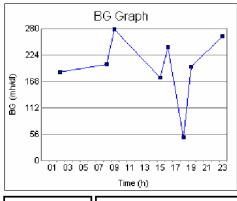
Start Date: 6/7/2002 End Date: 6/14/2002

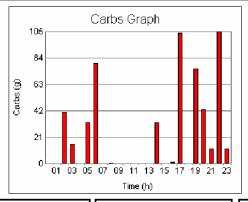
DATE	RC	00:00	01:00	02:00	03:00	04:00	05:00	06:00	07:00	08:00	09:00	10:00	11:00	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00	20:00	21:00	22:00	23:00	DAY
6/7/2002	BG	67	129		207	237					79	63531.00.000	2		169				267	269				280		198
5	СН			186			103						113					27								580
ð	INS			5.8		4.1			9.5								0.8	3.6	8.1				3.3	3.9		54
6/8/2002	BG	211							93	60	2.		145			65		109	206			187			233	156
1	СН			86		1	187					116						140								591
	INS					3.4		10.1			4.1			8.7	11.2	7.1	5.1				12.1					8
6/9/2002	BG			187			127	242	204		121		200						118	146	288		225			185
8	СН	154	101		42					237			31		119											687
	INS		2.9			9.8	12.3				3.7	8.1				14.9		8.6			10.0	3.3				82
/10/2002	BG				235						1		58	<u> </u>	190				284			294		96	101	178
	СН	102	87	117	78	122												113		10777070						620
	INS	3.0			6.1	10.7	13.7			14.3	14.8		0.7							11.6			2.5			90
/11/2002	BG					178	104	255			189		118	9			159			153		174		263		174
8	СН	141	156	147				42	46																	600
	INS	8.7					1.1					9.4	10.1		13.7		11.1			1.1	14.2	5.4				78
/12/2002	BG		5	191						149	22		174	59				112	83	217	94	194		£	197	147
	СН	99	167						84	kanas anas		83	37	10000000			133			r naznan			10000000			605
3	INS			14.1	30.0000000					6.9	4.2	12.0					6.7	0.6		6.6	12.2				6.6	76
/13/2002	BG		57							192	63		59				218		270	81		114				139
8	СН	63	118			32	66										29									528
	INS							9.4		7.7				2.0	1.4			7.0		13.8	3.4				5.5	67
AVG.	BG	139	111	188	239	207	128	248	185	151	146		121	59	179	65	185	153	216	152	193	192	225	194	198	168
3	СН	112	141	98	80	52	138	57	65	119		99	69		119		81	93								95
3	INS	5	2	8	9	7	10	9	10	10	6	10	5	7	9	11	5	4	8	8	8	4	2	6	6	

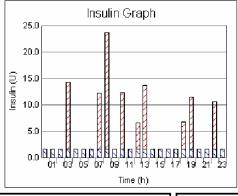
Daily Report

Animas

Daily report for: Annie Maas Date: Friday, 6/14/2002







BG	Log	Mea	ıl Log			
Time	BG Val	Time	Carbs	Fiber	Proteins	Calories
02:19	205	02:06	34	4	12	239
02:47	172	02:15	6	7	19	152
08:46	204	03:03	16	4	16	218
09:32	278	05:32	33	7	9	251
15:12	136	06:44	44	9	4	275
15:44	218	06:53	35	3	4	102
16:57	240	08:24	0	1	12	95
18:02	50	14:31	17	4	15	56
19:28	199	14:38	16	2	11	197
23:39	264	16:04	1	6	16	58
		17:08	59	0	16	28

Activity Log						
Time	Activity	Duration				
08:12 12:04 23:26	Test Activity Test Activity Test Activity	91 50 10				

Insulin Log							
Time	Туре	Units					
03:52	Е	12.7					
07:10	I	10.6					
08:19	I	10.8					
08:29	E	11.3					
10:51	I	10.7					
12:41	E	5.0					
13:06	E	12.1					
18:06	E	5.1					
19:52	В	9.8					
22:40	I	9.0					
ı							

Notes	
02:05 This note is the note test	
number 2 for 6/14/2002.	
10:27 This note is the note test	
number 1 for 6/14/2002.	
10:44 This note is the note test	
number 3 for 6/14/2002.	
11:53 This note is the note test	
number 5 for 6/14/2002.	
16:08 This note is the note test	
number 4 for 6/14/2002.	

ime (h)		
	Basa	al Rt.
test	Time	U/h
test	00:00	1.60
test		
test		
test		



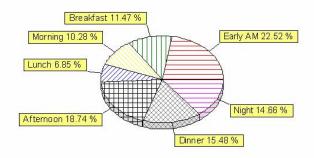
Distribution report for: Annie Maas

Start Date: 6/7/2002 End Date: 6/14/2002

Insulin Intake Distribution

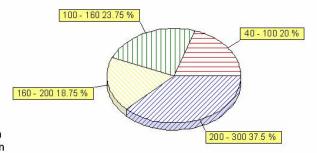
Extended Bolus 26.74 % Basal 32.82 %

Carbohydrates Distribution



The Insulin Intake Distribution graph shows the insulin distribution between various intake methods over the selected period of time. The Basal total is computed using the Active program selected in the Basal Programs screen.

Blood Glucose Levels Distribution

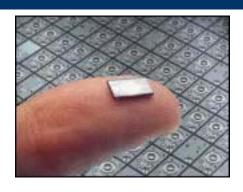


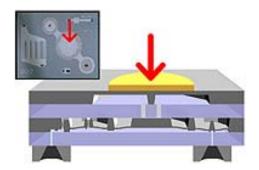
The Carbohydrates Distribution graph shows the distribution of carbohydrates intake between the time intervals set in the Settings screen. The time intervals used for this report are listed below (hours in 24h format).

Early AM
Breakfast
Morning
Lunch
Afternoon
Dinner
Night

The Blood Glucose Levels Distribution graph shows the distribution of blood levels between the BG intervals set in the Settings screen. The BG intervals are described in the graph labels, next to the percentage values.

Debiotech





Insulin Nanopump™

- Technology purchased by Animas in 2005.
- Based on the <u>MEMS Nanopump™ technology</u>-(Micro-Electro-Mechanical System) a highperformance micropump.
- Small size and weight.

ACCU-CHEK'Spirit



ACCU-CHEK™ Spirit Insulin Pump System

launched 10/31/2006

- ACCU-CHEK Spirit insulin pump
- Palm[®] PDA or optional smartphone
- ACCU-CHEK Pocket
 Compass software with bolus calculator
- Choice of ACCU-CHEK blood glucose meter
- Accu-Chek Pump Configuration Software



* Smartphone shown is an extra-cost option

ACCU-CHEK'Spirit



- Holds up to 315-units of insulin
- 0.1 U is smallest basal and bolus increment
- Side-mounted tactile buttons
- Reversible display
- Programming and customization easier with Accu-Chek Pump Configuration Software

Pump Functions	STANDARD Menu	ADVANCED Menu	CUSTOM Menu
Standard Bolus	•	•	•
Extended Bolus		•	•
MultiWave Bolus		•	
Temporary Basal Rate	•	•	•
Information	•	•	•
Change Basal Rate Profile		•	•
Program Basal Rate Profile 1	•	•	•
Basal Rate Profile 2		•	•
Basal Rate Profile 3		•	
Basal Rate Profile 4		•	
Basal Rate Profile 5		•	
Alarm Clock		•	•
Set Time & Date	•	•	•
Setup Menu Standard	•	•	•
Setup Menu Advanced		•	
Select User Menu	•	•	•

ACCU-CHEK Pocket Compass software with bolus calculator

- Palm® PDA or optional smartphone
- Convenient bolusing from a remote device
- Bolus calculator (not accessible from the pump)
- "Standard" boluses given via the pump are not factored into the IOB
- Daily insulin totals displayed in units, not percents (bolus total includes both the meal and the correction)



ACCU-CHEK Pocket Compass software with bolus calculator

- Electronic diary
- Customizable "adjustment" factors (stress, exercise)
- There is a low BG "manager" that recommends carb intake for low blood sugar
- Calorie King software can be loaded onto PDA as a reference (not carb counter)



Uploads and Downloads



- User tests BG.
- 2. BG is then uploaded to PDA from the meter via IR ("import").
- Bolus calculator makes recommendation.
- 4. Bolus amount is then transmitted to pump by IR.
- 5. PDA and meter data transmitted to PC.

MiniMed Paradigm® REAL-Time

System



1. Glucose Sensor



2. RF Transmitter





4. CareLink® and **Solutions® Therapy Management Software**



3. Glucose Meter



MiniMed Paradigm 522/722

- 522 holds up to 176 units/722 holds up to 300 units
- Basal increments 0.05 but bolus increments 0.1
- Intuitive menu with less scrolling
- Bolus Wizard: bolus calculator
- Tracts insulin on board
- History: total carbs, TDD, %meal, %corr, %basal
- BD meter transmits BG directly
- Optional remote for remote bolusing
- Optional Real Time CGM (MiniLink approved 2/2007)

CareLink® Personal Software

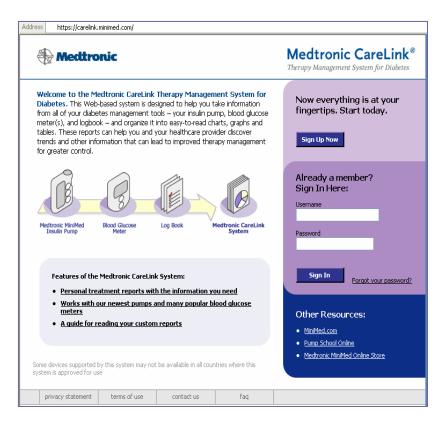
- Secure, online tool that integrates pump, meter, sensor, and logbook data into a series of reports
- Downloads can take place at patients homes
- Link to access downloads can be emailed to provider
- 13 different meters are compatible with CareLink software

How to access CareLink® Personal Software

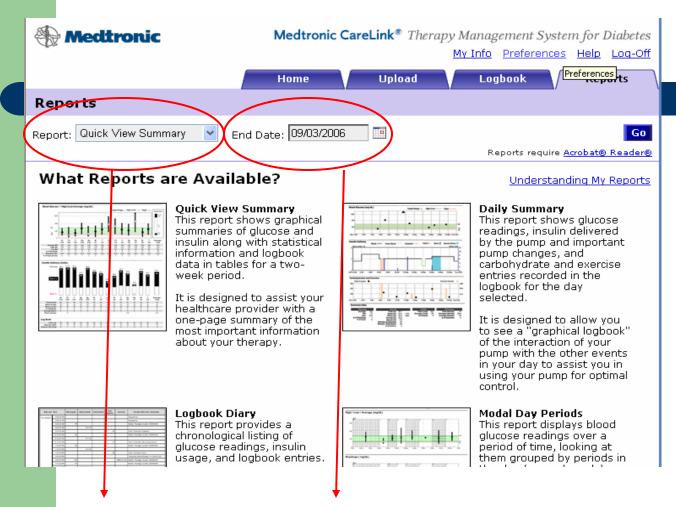


http://www.minimed.com to access Carelink Online from main home page

http://carelink.minimed.com



Choose Report and Time Ranges

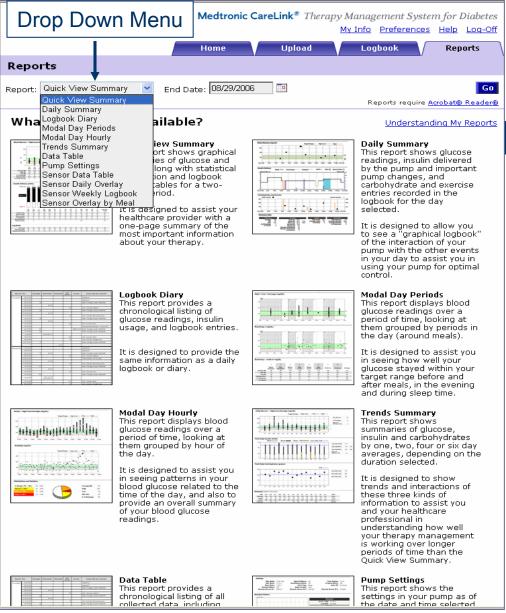


Press "Go" To Generate the Reports

Name of Report

Time Range Desired for Report

12 Types of Reports



Bolus Wizard Settings

Bolus Wizard

Bolus Wizard On
BW Setup Status Complete

BG Units mg/dL Carb Units grams Active Insulin Time 4 hours

Carbohyd	rate Ratio					
grams/Unit						
Time	Ratio					
12:00a	5					
11:30a	5					
04:30p	5					
-	-					
-	-					
-	-					
-	-					
-	-					

Insulin S	ensitivity
mg/dL p	er Unit
Time	Sensitivity
12:00a	30
12:00p	40
06:00p	30
-	ı
-	-
-	_
-	_
-	_

Blood Glucose Target									
mg/dL									
Time	BG Low	BG High							
12:00a	90	130							
-	-	-							
-	-	-							
-	-	_							
-	-	-							
-	-	-							
-	-	-							
-	-	-							

Sensor Settings

Sensor Feature On

Sensor ID 0001780

Cal Reminder On

Cal Time Reminder 10 minutes

High Glucose Limit On

High Glucose Value 240 mg/dL

High Glucose Snooze 90 minutes

Low Glucose Limit On

Low Glucose Value 90 mg/dL

Low Glucose Snooze 10 minutes

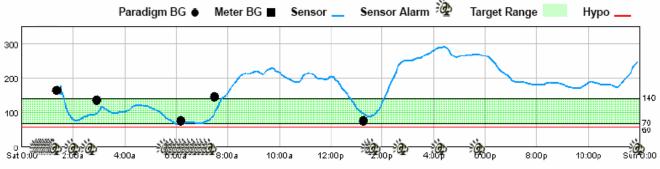
BG Units mg/dL

Missed Data 30 minutes

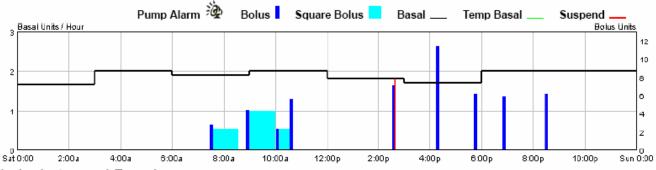
Alarm Snooze 10 minutes

Daily Summary

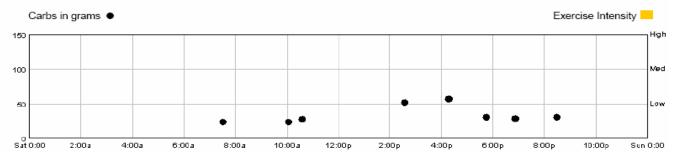
Glucose (mg/dL)



Insulin Delivery

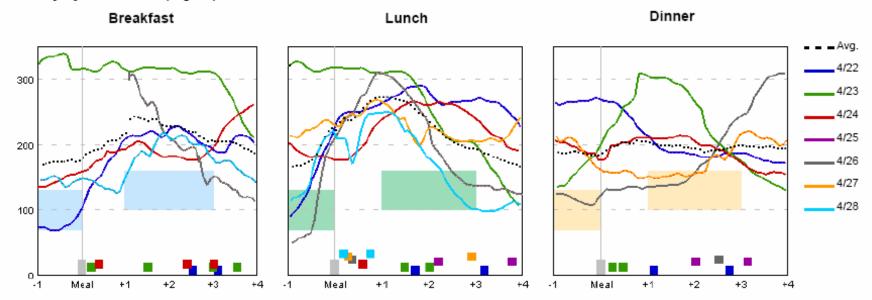


Carbohydrates and Exercise



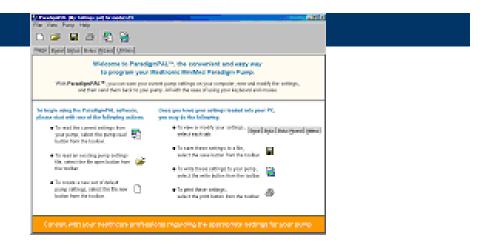
Sensor overlay by meal

Overlay by Meal Event (mg/dL)



	Sleeping 3:00 AM - 6:00 AM	Before Breakfast	After Breakfast	Before Lunch	After Lunch	Before Dinner	After Dinner	Evening 11:00 PM - 3:00 AM	All Time Periods
Range	100 - 150	70 - 130	100 - 160	70 - 130	100 - 160	70 - 130	100 - 160	100 - 150	
Average SG	146	173	227	190	234	186	195	162	185
High SG	248	340	318	326	312	270	302	308	340
Low SG	56	68	138	48	100	106	134	72	48
Standard Dev.	50	95	51	76	50	51	42	59	65
# of Readings	180	48	119	72	144	60	120	252	995

ParadigmPAL™ Software



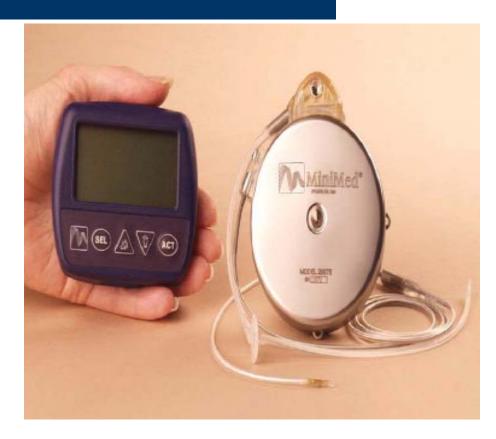
- PC based application
- Allows you to view, modify, back up, and program the Paradigm pump
- Once pump settings adjusted, they are transmitted to pump using Paradigm Link Blood Glucose Monitor or ComLink device

Pediatric Models: 522K and 722K - Available May 2007

Previously approved for only adult patients, CGM will soon be available in models specifically for children and teenagers ages 7-17 as part of the MiniMed Paradigm® REAL-Time System, the world's only system combining an insulin pump with continuous glucose monitoring! REAL-Time CGM offers important therapeutic benefits. The pediatric insulin pump models with REAL-Time functionality for children and teens will be denoted with a "K" for "Kids" (model 522K or 722K).

Medtronic Implantable Insulin Pump

- In US, over 300 research subjects implanted with Medtronics Internal Insulin Pump
- Today approximately 35 patients still have their devices implanted.
- Hockey puck-sized device implanted under the skin of the abdomen
- Delivers insulin to hepatic portal circulation via peritoneal cavity.
- Uses specially concentrated insulin approved in Europe.
- Pump refilled every 2-3 mos.
- Insulin delivered in short bursts throughout the day and at higher amounts at mealtimes.



Medtronic Implantable Pump



- In Europe the Medtronic Internal Insulin Pump is approved for use.
- Not FDA approved for use in the US.
- Medtronics recently announced they are terminating the implantable pump study in the U.S.
- Patients will need to return their pumps to Medtronics by July 1, 2007.
- www.theiipump.com

Deltec Cozmo® Model 1800 Insulin Pump







New Deltec Cozmo® Model 1800



The same in many ways......

- Attachable FreeStyle glucose meter with direct meter entry
- 300-unit cartridge
- Easy to read LCD display
- Correction and meal bolus calculator
- No-look, "touch" boluses
- IR connection to PC for data download
- Personalized reminders and alerts

New Cozmo® Model 1800 Features

Launched January 2007

- CoZmanager 2.0 PC Communications Software
- Hypo Manager
- Disconnect
- Basal Test
- Therapy Effectiveness Scorecard
- Weekly Schedule
- Enhanced Meal Maker with CozFoods List

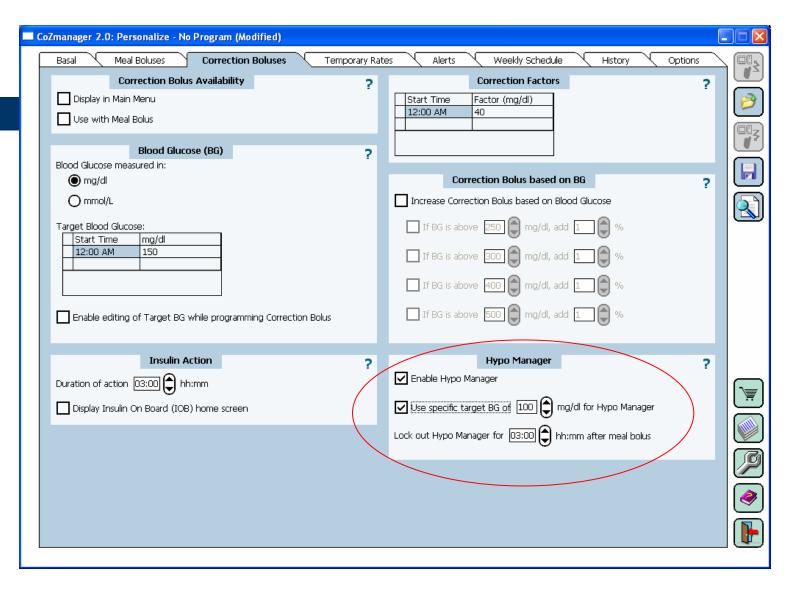


Hypo Manager™ Feature



- Monitors for carbohydrate deficit or insulin excess at each blood glucose test.
- If blood glucose is below target, recommends an amount of carbohydrate to correct hypoglycemia.
- Can prevent over-treating lows
- After a blood glucose test, if there is insulin excess, recommends an amount of carbohydrate to prevent hypoglycemia.

Hypo Manager™ Feature



Disconnect

- This feature will allow a patient to take a portion of their projected basal insulin prior to disconnecting.
- Calculates for disconnections of 15 minutes or more, up to 2 hours.
- When the patient reconnects, patient reminded to test BG (correction bolus recommended on missed basal and high blood glucose if needed).
- Missed basal delivered is included in Insulin On Board whether given at disconnection or reconnection.

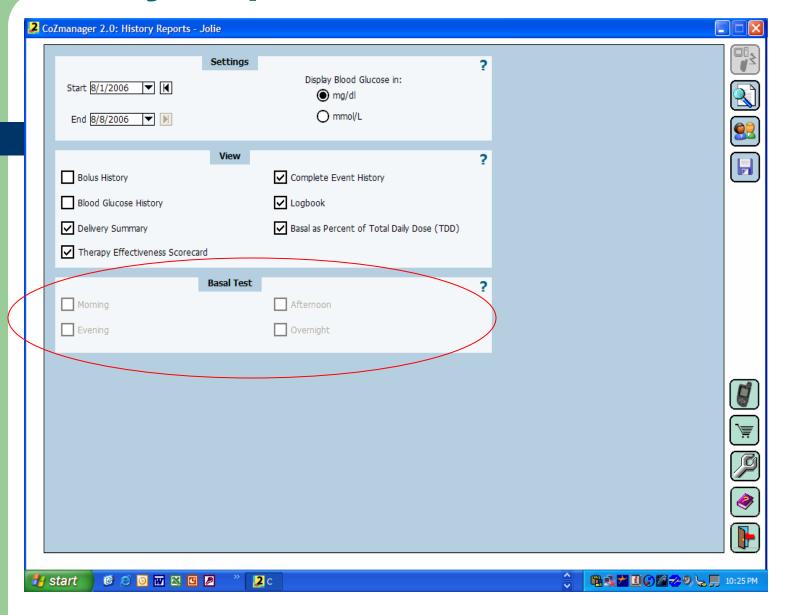
Basal Testing on the Deltec Cozmo® pump

- In-pump guide to simplify basal rate testing
- Patient gets a reminder to test BG q 2-3 hours
- Test automatically ends when:
 - 1. BG exceeds the "High" limit
 - 2. BG falls below the "Low" limit
 - 3. If bolus is given
 - 4. If battery or cartridge changed

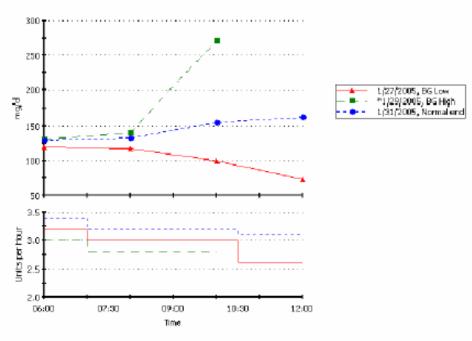
Basal Testing on the Deltec Cozmo® pump



History Reports



Basal Rate Test - Morning Pump User Name: Daphne Pump User ID: 1/8/2005 - 7/25/2005



^{*} There was insulin on board at the time of the first BG reading. For details, refer to the log below.

1/31/2005	12:00:00PM	End test - Normal
1/31/2005	12:00:00PM	Blood Glucose from CoZmonitor 163 mg/dl
1/31/2005	10:30:00AM	Basal rate changed to 3.10 units/hour
1/31/2005	10:00:00AM	Blood Glucose from CoZmonitor 155 mg/dl
1/31/2005	MA00:00:8	Blood Glucose from CoZmonitor 133 mg/dl
1/31/2005	7:00:00AM	Basal rate changed to 3.20 units/hour
1/31/2005	6:00:00AM	Basal rate at test start 3.40 units/hour
1/31/2005	6:00:00AM	Basal test started
1/31/2005	6:00:00AM	IOB at first BG Reminder 0.0 units

3/14/2006 7:29:32AM Page 1 of 3

Therapy Effectiveness Scorecard

- Quick & easy analysis tool to help modify pump settings
- Look up last 2-30 days
- Report accessible on CoZmanager® 2.0 software of directly on the pump.

Therapy Effectiveness Scorecard







Therapy Effectiveness Scorecard

Pump User Name: Scott K. Johnson

Pump User ID:

2/7/2007 - 2/14/2007

8 Day Averages

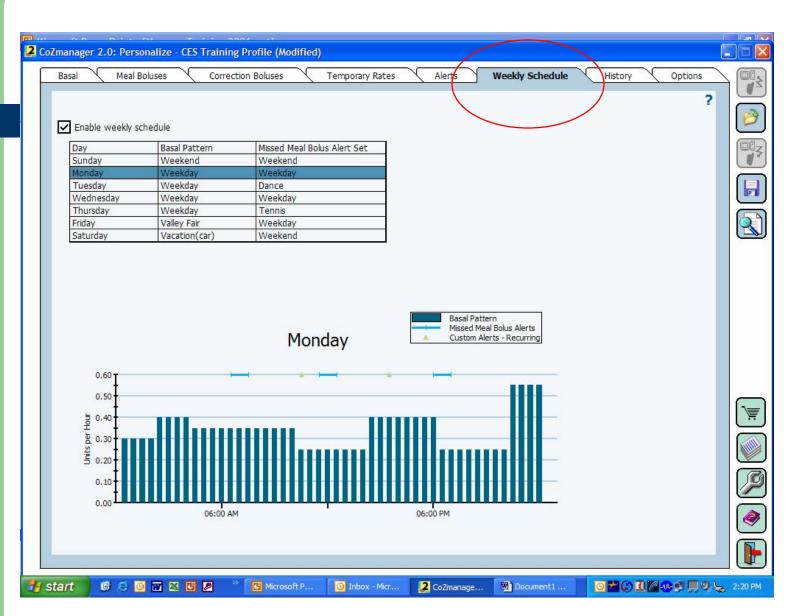
Carbohydrates per day 340 grams Total Daily Dose 71.94 units Meal Bolus 55.44% Correction Bolus 3.80% Basal 40.76% Blood Glucose 136 mg/dl BG tests per day 4.0 BG Standard Deviation 67 mg/dl

2/22/2007 6:37:44PM Page 1 of 1

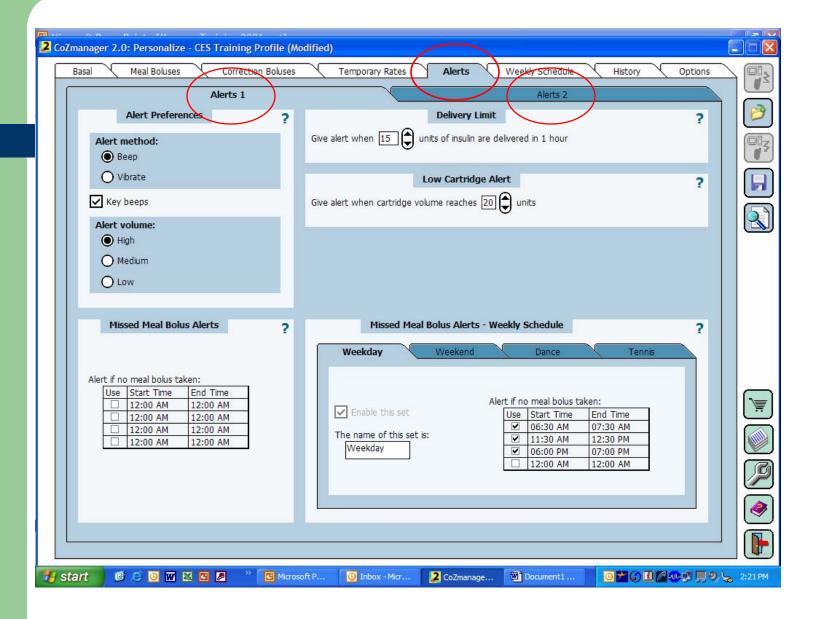
Weekly Schedule

- Allows you to assign basal profiles to days of the week
- The profile will automatically change when the day of the week changes
- Custom alerts can also be assigned by day of the week
- Great for school children, shift workers or other schedule variations

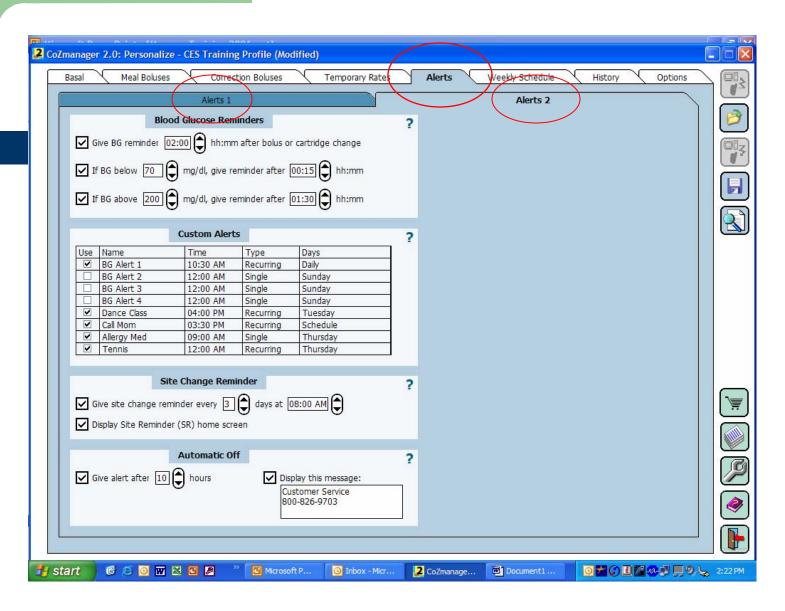
Weekly Schedule



Alerts 1



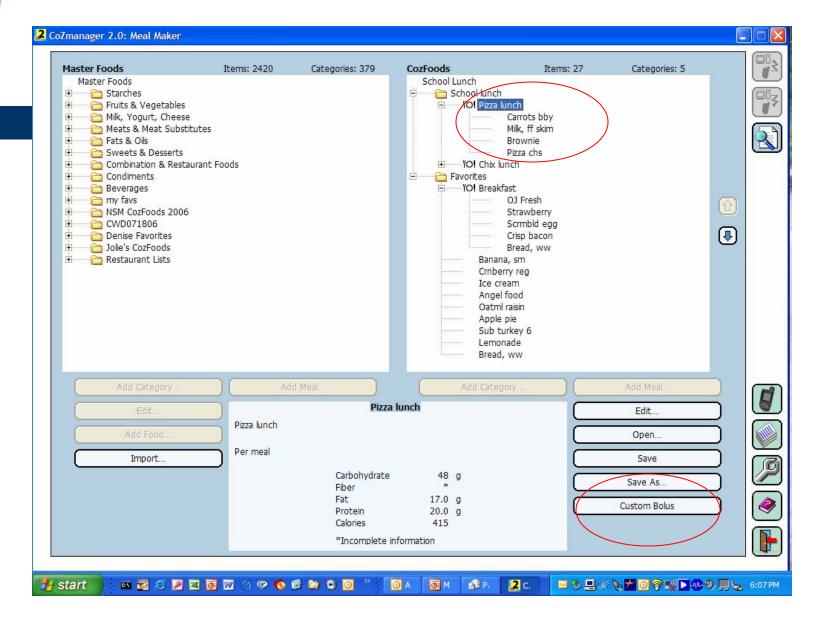
Alerts 2



Enhanced Meal Maker® with CozFoods™ List

- Meal Maker: tallies carbs as foods are selected from food list
- CozFoods™: food list with carb content that can be downloaded into pump
- Default database of 400 foods
- Additional foods must be entered manually to "Master Food List" with CoZmanager® 2.0
- Up to 600 items can be downloaded to pump

CozFoods



CozFoods download

 When sending information to Cozmo, you may either select CozFoods, the Pump Program, or both





OmniPod Insulin Management System



OmniPod Insulin Management System



PDM

- Wireless, handheld device transmits personalized insulin delivery instructions
- Incorporates a FreeStyle glucose meter

"Pod"

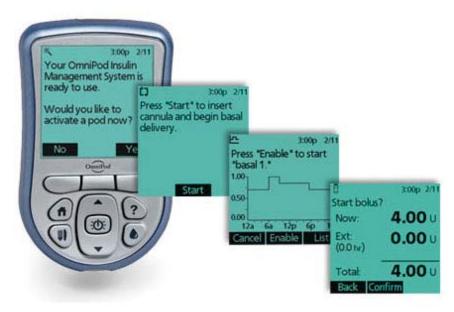
- Light-weight, selfadhesive, insulin reservoir
- Self contained cannula, insertion needle, battery and pump motor



"Pod"

- Holds up to 200 units of insulin
- Can be worn on abdomen, arm, thigh, lower back
- Worn for 3 days or 80 hours (previously 72 hr)
- Automatic priming and cannula insertion
- Watertight
- NO TUBING = "Freedom"

PDM



- Large easy to read display with backlighting
- Suggested bolus calculator (direct BG integration)
- 1000 food database (reference only)
- Stores and displays BG and total daily insulin and carbs (no software for analysis yet)
- Fits easily into pocket or purse
- Does not need to be with in certain distance of "Pod" to transmit basal insulin

"Changing your OmniPod couldn't be simpler"



1. Fill new OmniPod with insulin.



2. Apply the OmniPod to your skin.



3. Press "Start" on the PDM for automated cannula insertion.

OmniPod "Pay-As-You-Go"

 Eliminates the large upfront cost of conventional insulin pumps

Automated Cannula Insertion

Valeritas' h-Patch™

"Make it simple and people will use it."

- Already has FDA approval.
- Will be initially marketed to T2D.
- Disposable, waterproof device as small as ChapStick™ tube.
- "Attractive alternative to other insulin delivery methods such as catheter-based electronic pump systems or injections."



Valeritas' h-Patch™



- Patient peels protective liner from the adhesive backing.
- Start button is pushed, micro-needle is inserted and basal insulin starts.
- Can be attached to abdomen, arm or thigh.
- Wearer presses the bolus button and a click will be heard to indicate bolus has been delivered.
- Replaced every 24 hours.

Where next?

- Closed loop?
- Dual chamber pumps
- Faster acting insulins (Biodel)
- More sensor augmented pumps (Will Cozmo and OmniPod "marry" Navigator?)

Pens, Pumps and Dosing Software: The Latest Advances

Andrea Gasper, MS,PA-C andreamgasper@yahoo.com

Debra Armstrong, RN, CCRN