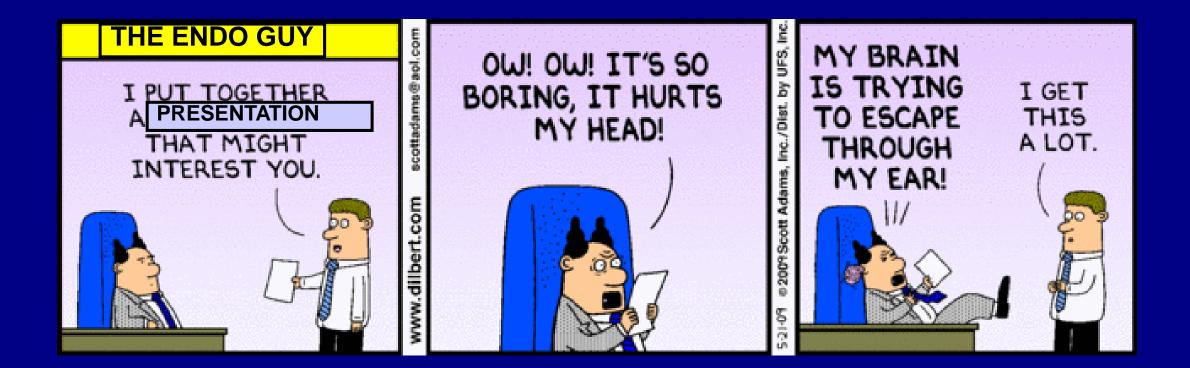
Current (and Future?) Treatment of Children With IDDM

> Bernard M. Degnan, MD Pediatric Endocrinology Ascension St. John Health System

Financial Disclosure



Some definitions

- Diabetes: to pass through
- Mellitus : sweet (from the Greek word for honey)
- Insipidus: having no taste
- Guess how ancient Greek doctors distinguished between diabetes mellitus and diabetes insipidus??

Insulin Physiology Effects

- Protein: Anabolic- enhances muscle amino acid uptake (especially branched chain AAs)
- Carbohydrate: Inhibits glycolysis, and stimulates glucose uptake in adipose, muscle, splanchnic tissues
- Fat: Inhibits hormone-sensitive lipase, stimulates free fatty acid uptake, and inhibits ketogenesis in liver

Effects and Symptoms of Insulin Deficiency

- Hyperglycemia: weight loss, polyphagia, polyuria/polydypsia. Irritability, headache are common
- Ketosis and/or ketoacidosis (DKA): abdominal pain, nausea, vomiting, sweet breath (acetone formed via Acetoacetate), dyspnea / Kussmaul respiration
- Muscle Breakdown for Glucose substrate: weakness, ill appearance

Diabetes in the US

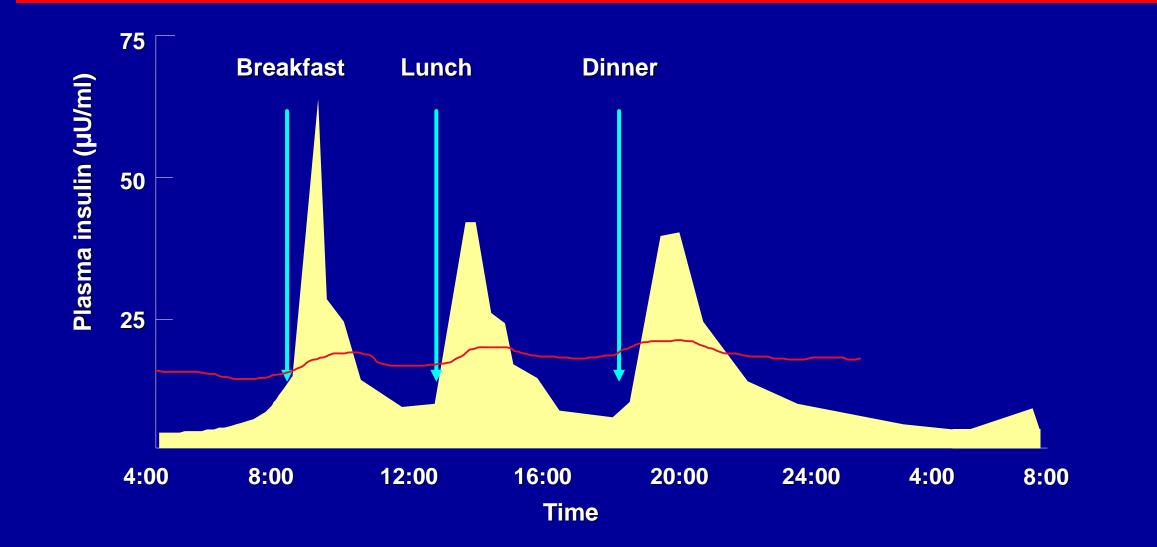
- 8.5% of US population has type 2 diabetes
- 0.4% have type 1 diabetes (just under 1 million)
- Type 1 diabetes accounts for 2/3 of children <20 with diabetes (80% < 10 yo)

HOW DO WE TAKE CARE OF THIS?

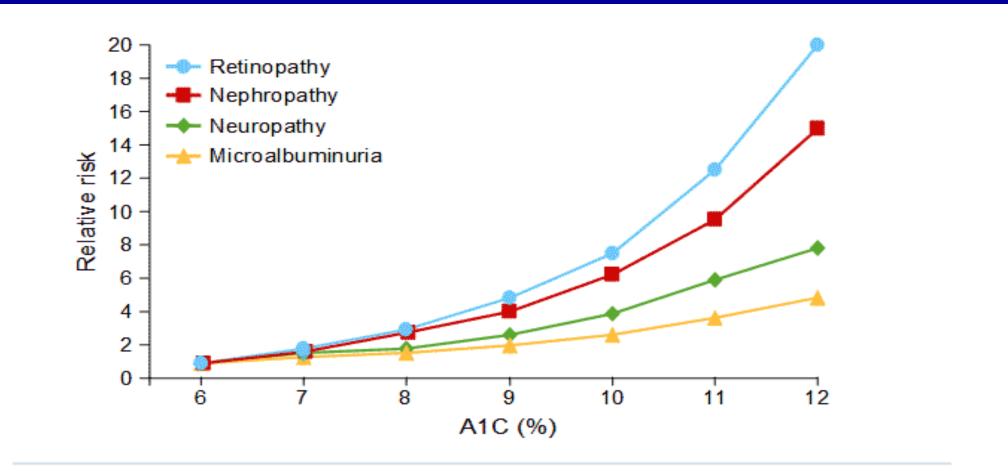
• INTENSIVE INSULIN THERAPY

- 1980's : two shots a day with NPH / Regular or maybe Lente or Ultralente
- 1990's : HUMALOG led to more frequent shots (lunchtime) and insulin pump therapy
- 2000's : Lantus use leads to initiation of intensive therapy at diagnosis

Physiological Serum Insulin Secretion Profile



Relative Risk of Progression of Diabetes Complications (DCCT)



DCCT Research Group, *N Engl J Med* 1993, 329:977-986.

Lifetime Benefits of Intensive Therapy (DCCT)

 Gain of 15.3 years of complication free living compared to conventional therapy

 Gain of 5.1 years of life compared to conventional therapy

DCCT Study Group, JAMA 1996, 276:1409-1415.

Lifetime Benefits of Intensive Therapy (DCCT)

- Reduce the risk of eye damage by more than 75 percent
- Reduce the risk of nerve damage by 60 percent
- Prevent or slow the progression of kidney disease by 50 percent
- Reduce the risk of diabetes-related heart attack and stroke by 50 percent

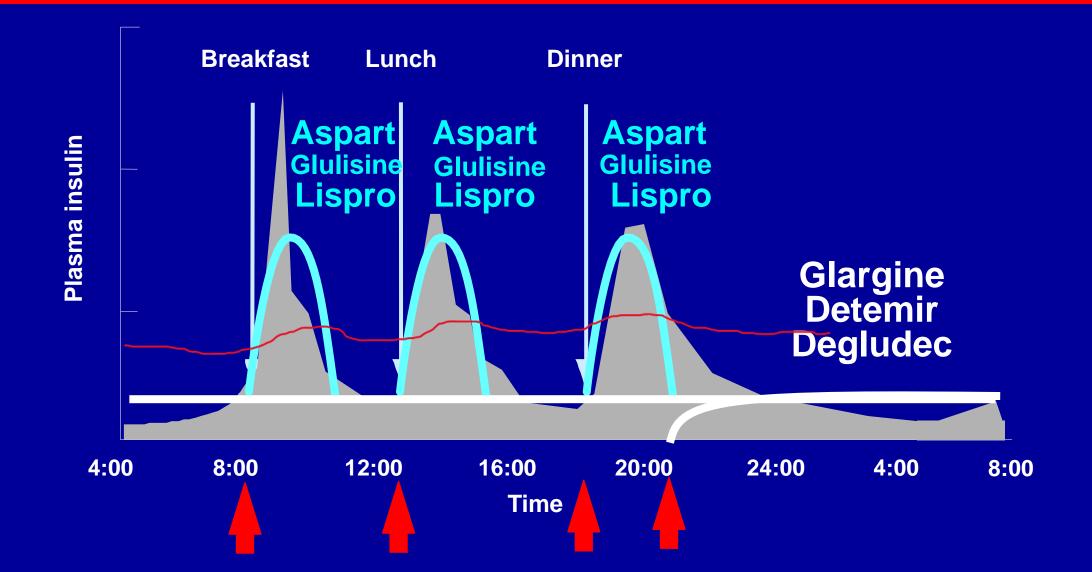
DCCT and EDIC

 Epidemiology of Diabetes Interventions and Complications (EDIC) study, has continued to follow DCCT participants for the last 20-plus years. EDIC has shown that there are long-term benefits of early and intensive blood glucose control on the future development of diabetes-related complications such as heart, eye, kidney, and nerve disease, and that early and intensive blood glucose control also lengthens life.

The Basal/Bolus Insulin Concept

- Basal insulin
 - Suppresses glucose production / release between meals and overnight
 - 40% to 50% of daily needs
- Bolus insulin (mealtime)
 - Limits hyperglycemia after meals
 - Immediate rise and sharp peak at 1 hour
 - 10% to 20% of total daily insulin requirement at each meal

Basal/Bolus Treatment Program with Rapid-acting and Long-acting Analogs



Comparison of Human Insulins and Analogs

Insulin Preparations	Onset of Action	Peak (hr)	Duration of Action (hr)
Lispro/Aspart/Glulisir	e* 5–15 min	1–2	<mark>4–6</mark>
Regular	30–60 min	2–4	6–10
NPH	1–2 hr	4–8	10–20
Glargine**	1–2 hr	"flat"	<mark>~24</mark>
Detemir***	1–2 hr	6-12	12-24
Degludec****	1-2 hr	"flat"	48Hr?

* "Rapid Insulin Analogs"-Lispro=Humalog/Admelog, Aspart=Novolog, Fiasp Glulisine=Apidra ** Glargine=Lantus, ***Detemir=Levemir, ****Degludec=Tresiba

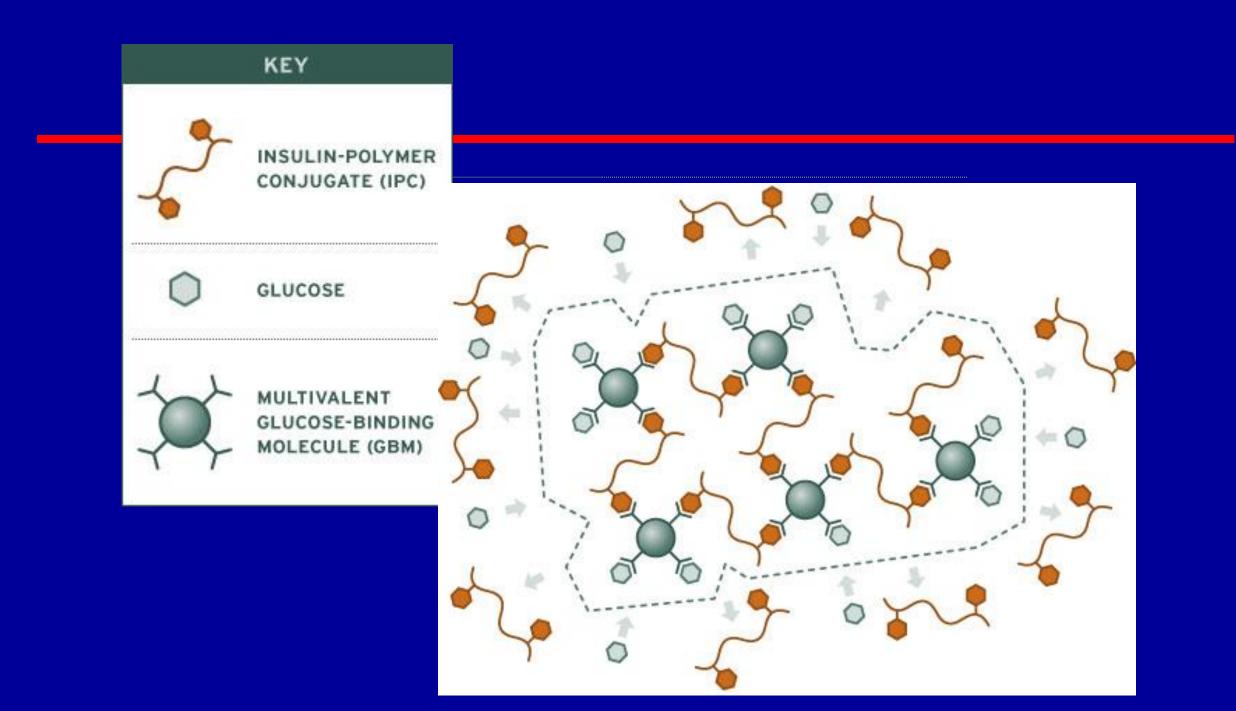
Note: Action of any insulin varies between and within people



University of Michigan C.S. Mott Children's Hospital

New forms of Insulin in development

- Ultra-long lasting
- Ultra-short acting
 - Intradermal
 - Intraperitoneal
- Oral insulin: more likely beneficial for Type 2
- Inhaled, intranasal
- Smart Insulin : "built-in" glucose sensors
 - Multi-valent glucose binding molecules



Inhaled Insulin



Starting MDI

- Starting total daily insulin dose is based on weight
 - 0.2 to 1.0 x wgt. in kg = Units / day
- Bolus dose (aspart/lispro/glulusine) = ~20% of starting dose at each meal
- Basal dose (glargine) = 40-50% of starting dose at bedtime or in AM (same time each day)

Estimating the Insulin to Carbohydrate Ratio

TDD = Total Daily Dose

Use the "500 Rule"

Insulin / Carb = 500 / TDD

Anywhere from 5 to 40 g carb is covered by 1 unit of insulin

In younger children, the ratio needed is usually higher than the formula predicts

Correction Bolus (for high glucose)

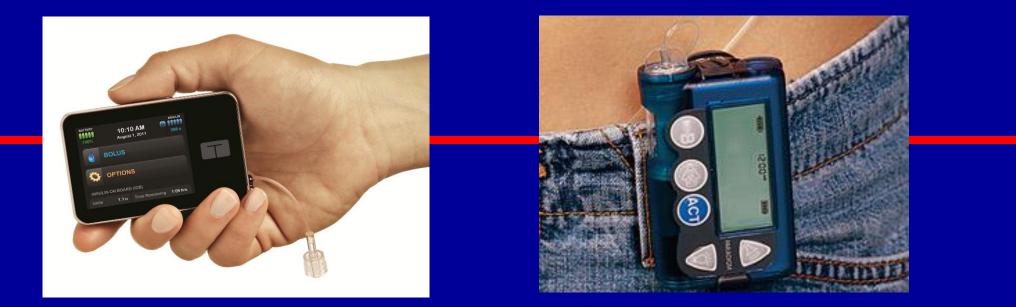
- Must determine how much glucose is lowered by 1 unit of short- or rapid-acting insulin
- This number is known as the correction factor (CF) or insulin sensitivity factor (ISF)
- Use the 1800 rule to estimate the CF
- CF = 1800 divided by the total daily dose (TDD)
 ex: if TDD = 36 units, then CF = 1800/36 = ~50
 meaning 1 unit will lower the BG ~50 mg/dl

In younger children, the correction factor is often higher than the 1800 rule predicts due to increased sensitivity









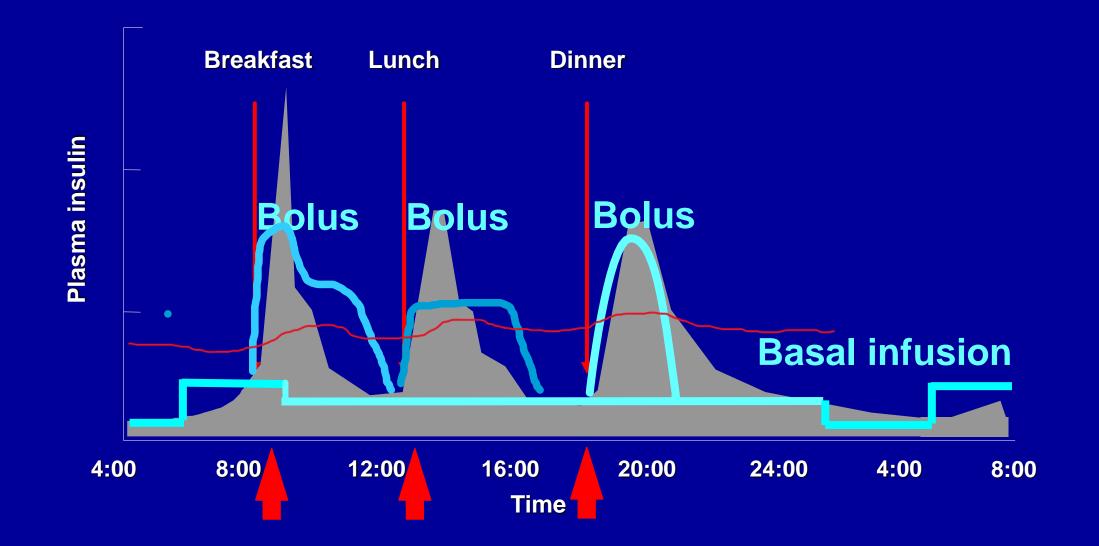




Pump Infusion Sets



Variable Basal Rate: CSII Program



Insulin Pump Profiles

- Basal rates
 - 12 AM = 0.8 Units/hr
 - 3 AM = 1.0 Units/hr
 - 9 AM = 0.7 Units/hr
 - 6 PM = 0.9 Units/hr
- Target
 - 12 AM = 100-150
 - 6 AM = 90-120
 - 9 PM = 100-150

- Carb Ratios
 - 12 AM = 20
 - 6 AM = 12
 - -10 AM = 15
 - 5 PM = 15
 - 9 PM = 20
- Sensitivity / Correction
 - 12 AM = 60
 - 6 AM = 50
 - 9 PM = 60

Insulin Pump instead of Syringe/Vial or Pen

Improved accuracy vs. syringes / Pens:

Insulin Pumps allow for much more flexible dosing, reduced risk of hypoglycemia; pens give 0.5 Unit increments at most

Precise insulin delivery (basal rates as low as 0.025 U/hr, boluses to nearest 0.1 unit)

Multiple basal profiles possible: adjust for sick day, exercise, shift hours, etc.

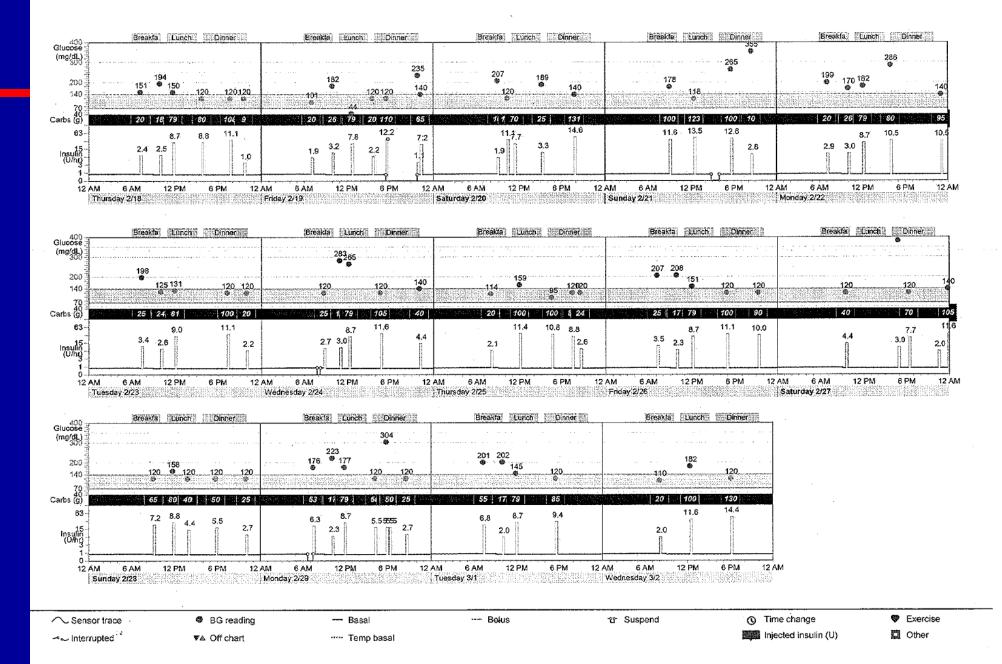
Extended boluses ("slow-release insulin dose") for high fat and high protein meals, or more than one bolus per meal

• Bolus calculators

- Once programmed with insulin to carbohydrate ratio (ICR) and Correction factor (CF), mistakes are minimized in dose calculation
- Insulin on Board Feature: designed to eliminate insulin dose stacking

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Sensor & Meter Overview (2 of 2)



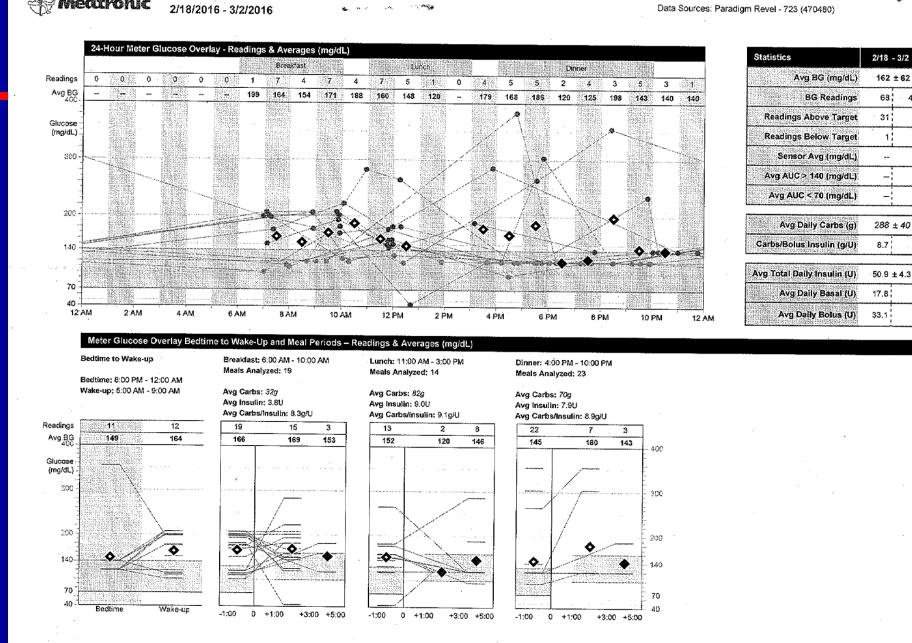
4.9/day

46%

1%

35%

65%



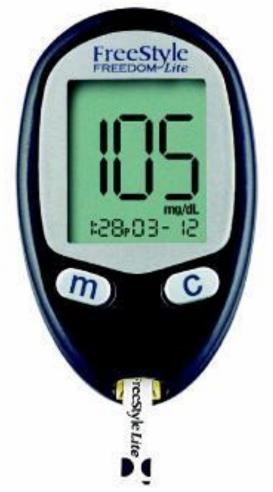
. 0.

— BG reading BG reading ▼▲ Off chart Average within target range Average outside target range

Sensor & Meter Overview (1 of 2)

A Medironic





Continuous Glucose Monitor

- 3 basic components
 - <u>Sensor</u> creates the signal (electric current is created based on how much glucose is present)
 - <u>Transmitter</u> plugs into the sensor and sends the signal through the air
 - <u>Receiver</u> shows the signal in a number or graph format:
 - Insulin pump (Medtronic 530G, t:slim G4, Animas Vibe)
 - Separate receiver (Dexcom G4 or G5 Mobile) or iPhone / Android (soon) (Dexcom G5 Mobile)
 - Remote viewing after data is sent to the "cloud"

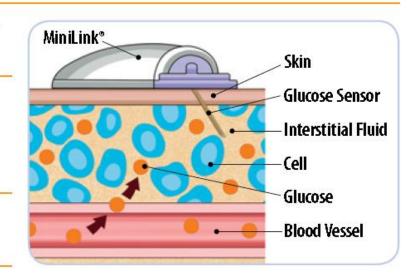
CGM is not the same as BG monitoring

Your BG meter measures glucose (sugar) levels in your **blood**, and your glucose sensor measures glucose levels in the fluid surrounding the cells in your tissue, which is called **interstitial fluid**.

Most of the time, glucose travels first to your blood and then to your interstitial fluid.

Because of how glucose travels, your BG meter readings and sensor readings will rarely match exactly. *This is normal and should be expected*.

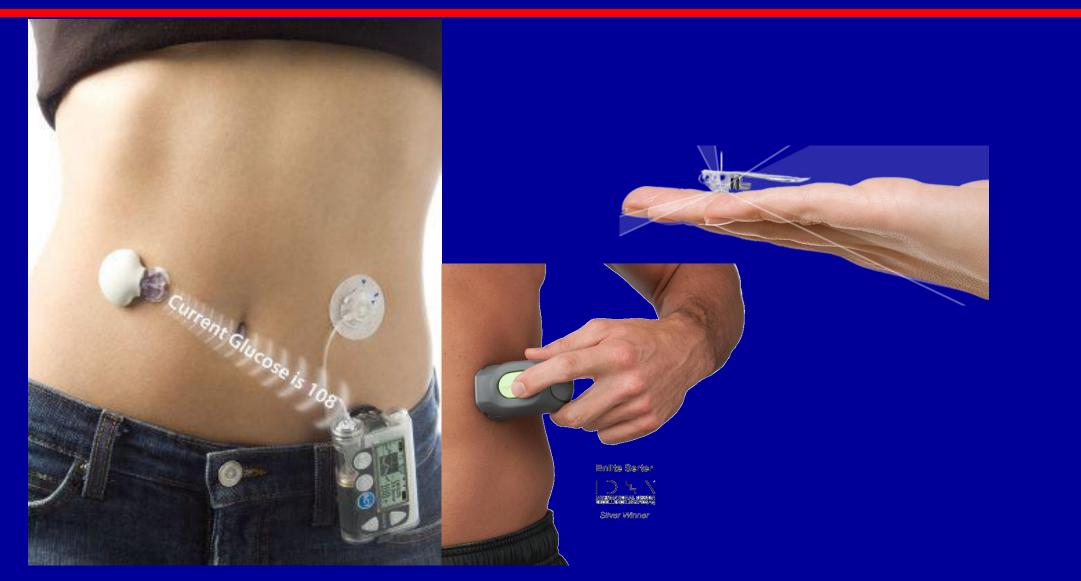
Usually your BG meter readings and your sensor readings will be close.



However, when glucose levels are rising or falling quickly, you should **expect** to see a larger difference between your BG meter value and the sensor glucose reading. Examples of times when this may occur include:

- After meals or after insulin
- When **†** or **↓** arrows appear on your pump screen

Medtronic Enlite Sensor



Guardian Connect CGM System from Medtronic

- 1. Guardian Connect App: glucose readings every 5 minutes, readout on a smartphone
- Guardian[™] Sensor 3 and Guardian[™] Connect Transmitter. Sensor usable up to seven days with a Bluetooth[®] transmitter
- Automatic uploads to CareLink[™] account; easily accessed on the website.
- 4. Smart technology to predict where glucose levels are headed, the system alerts patients from 10 to 60 minutes before a glucose excursion, so they can take action in advance.
- Sugar.IQ[™] Intelligent diabetes assistant app. Uses IBM Watson[™] technology. Reveals hidden patterns to provide personalized insights to help patients make smarter decisions.
- 6. Does not replace finger pokes for dosing



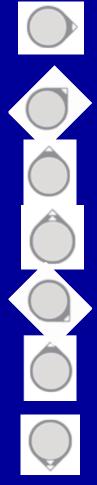
Dexcom G6



- Change site every 10 days
- 2-hour sensor warm-up period
- No calibration is required
- FDA approved to dose insulin
- Data viewable on the receiver or cell phone
- Acetaminophen DOES NOT interfere with glucose readings



<u>CGM Glucose Trend Arrows</u> Medtronic Dexcom



Constant: glucose is steady (not increasing/decreasing more than 1 mg/dL/min).

Slowly rising: glucose is rising 1-2 mg/dL/min

Rising: glucose is rising 2-3 mg/dL/min

Rapidly rising: glucose is rising more than 3 mg/dL/min

Slowly falling: glucose is falling 1-2 mg/dL/min

Falling: glucose is falling 2-3 mg/dL/min



Rapidly falling: Your glucose is falling more than 3 mg/dL/min

Constant: glucose is steady (not increasing/decreasing more than 1 mg/dL/min).

Rising: glucose is rising 1-2 mg/dL/min

Rapidly rising: glucose is rising more than 2 mg/dL/min



Rapidly falling: glucose is falling more than 2 mg/dL/min

PEDIATRIC WORKSHEET



ADJUSTING INSULIN DOSES USING DEXCOM G5[®] MOBILE TREND ARROWS

This is your worksheet based on the Endocrine Society approach¹ for making treatment decisions using the Dexcom G5[®] Mobile Continuous Glucose Monitoring (CGM) System. F00D + CORRECTION + ARROW = TOTAL INSULIN DOSE

STEP 1: Calculate your rapid-acting insulin dose for food and corrections as prescribed by your healthcare professional. STEP 2: Add or subtract insulin based on your trend arrow.

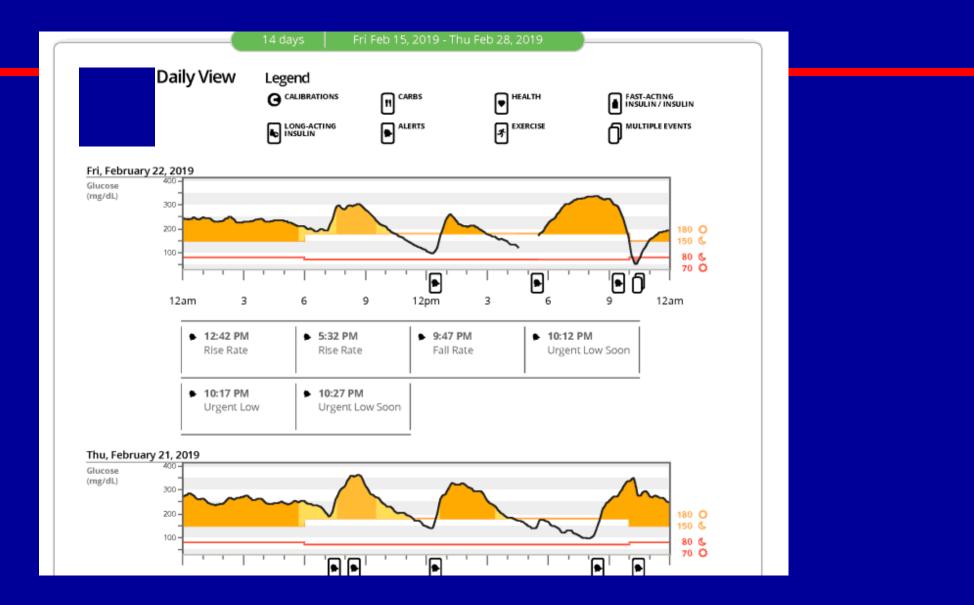
Do not take any additional insulin until at least ______ hours from last dose.

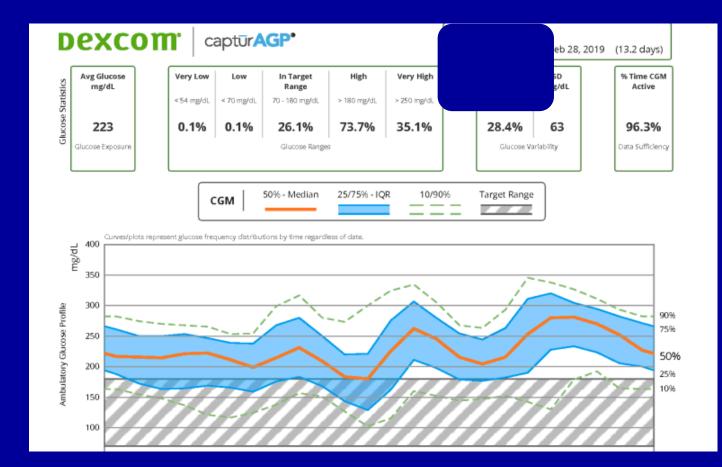
ADJUSTING INSULIN DOSES USING TREND ARROWS: PRE-MEAL AND AT LEAST 3 HOURS POST-MEAL.

ARROW DIRECTION	CHANGE IN GLUCOSE	CORRECTION INSULIN DOSE FACTOR ADJUSTMENT (U)		NOTES	
A		□ less than 25	□ +4.0	Example: If your correction factor is 1:50	
		□ 25-49	□ +3.0	you will add 2.0 units of insulin for the double up arrows.	
	Increasing >3 mg/dL/min	□ 50-74	□ +2.0		
	>5 mg/uL/min	□ 75-124	□ +1.0		
RAPIDLY RISING		□ over 125	□ +0.5		
A		□ less than 25	□ +3.0		
	Increasing	□ 25-49	□ +2.0		
	2–3 mg/dL/min	□ 50-74	□ +1.0		
	2-3 mg/dL/mm	□ 75-124	□ +0.5		
RISING		□ over 125	No adjustment		
	With south a set	□ less than 25	□ +2.0		
	Increasing	□ 25-49	□ +1.0		
	1–2 mg/dL/min	□ 50-74	□ +0.5		
SLOWLY RISING		□ 75-124	No adjustment		
		□ over 125	No adjustment		
0	Not increasing/ decreasing >1 mg/dL/min	□ less than 25	No adjustment		
		□ 25-49	No adjustment		
		□ 50-74	No adjustment		
		□ 75-124	No adjustment		
STEADY		□ over 125	No adjustment		
0		□ less than 25	□ -2.0		
	Decreasing	□ 25-49	□ -1.0		
	1–2 mg/dL/min	□ 50-74	□ -0.5		
		□ 75-124	No adjustment		
SLOWLY FALLING		□ over 125	No adjustment		
Q	Decreasing 2–3 mg/dL/min	□ less than 25	□ -3.0		
		□ 25-49	□ -2.0		
		□ 50-74	□ -1.0		
		□ 75-124	□ -0.5		
FALLING		□ over 125	No adjustment		
\cap		□ less than 25	□ -4.0		
		□ 25-49	□ -3.0		
	Decreasing >3 mg/dL/min	□ 50-74	□ -2.0		
Y	20 mg/dL/min	□ 75-124	□ -1.0		
RAPIDLY FALLING		□ over 125	□ -0.5		

See Back







Freestyle Libre





- Less expensive
- 1 hour "warm up"
- No calibrations needed
- 14 day wear
- You must request (swipe) the data
- NO ALARMS

Freestyle Libre Continuous Glucose Monitoring System

- ✓ No finger stick BG calibration is required for the Freestyle Libre.
- ✓ If the CGM reading is <80 or >300 mg/dl or if there is any question regarding accuracy, a finger stick BG check should be done immediately.



American Diabetes Association, 3



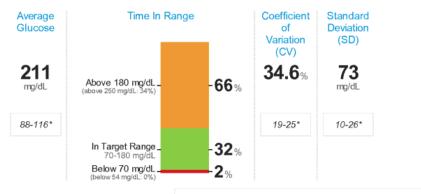
Users can download an app to iPhone to use the phone as the scanner! FreeStyle LibreLink



CGM Device: FreeStyle Libre Pro [N/A]% Compliant w/Calibration* 100% Time Worn

*Not applicable to FreeStyle Libre or FreeStyle Libre Pro which do not require calibration.

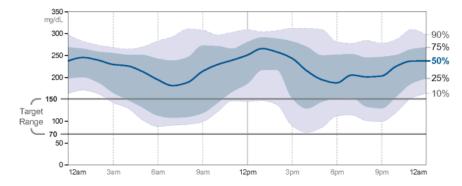




*Reference ranges calculated from population without diabetes.

Ambulatory Glucose Profile

Curves/plots represent glucose frequency distributions by time regardless of date



Medtronic 670G

MINIMED 670G SYSTEM HIGHLIGHTS.

The MiniMed 670G system with SmartGuard® HCL technology offers two new levels of personalization:

NEW! The Suspend before low⁵ option avoids lows and rebound highs proactively by automatically stopping insulin 30 minutes before you reach your preselected low limits, then automatically restarts insulin when your levels recover, all without bothersome alerts.

NEW! The **Auto Mode**[‡] option automatically adjusts your basal insulin delivery every 5 minutes based on your sugar levels to keep you in target range, all day and night.

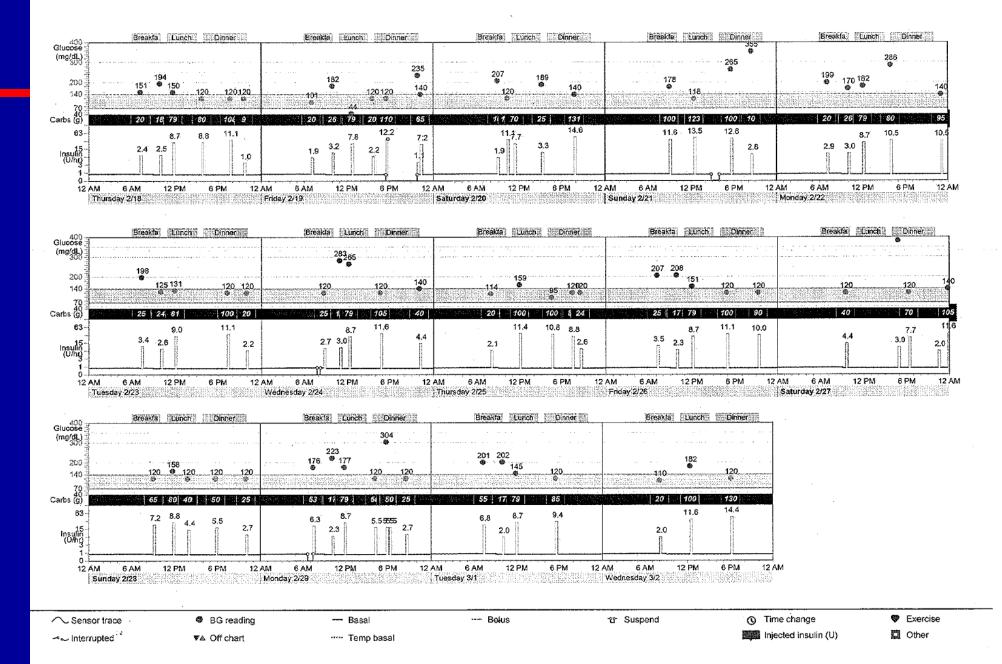


NEW! Guardian® sensor 3 continuous glucose monitoring sensor. Introducing the most accurate sensor from Medtronic, now with up to 7 day wear and easy insertion. It is the FIRST and ONLY continuous glucose monitoring sensor FDA approved and trusted to control insulin dosing.

Exclusive CONTOUR®NEXT LINK 2.4 meter¹ Get easy and accurate CGM calibration, insulin dosing and remote bolusing with our exclusive meter.

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Sensor & Meter Overview (2 of 2)



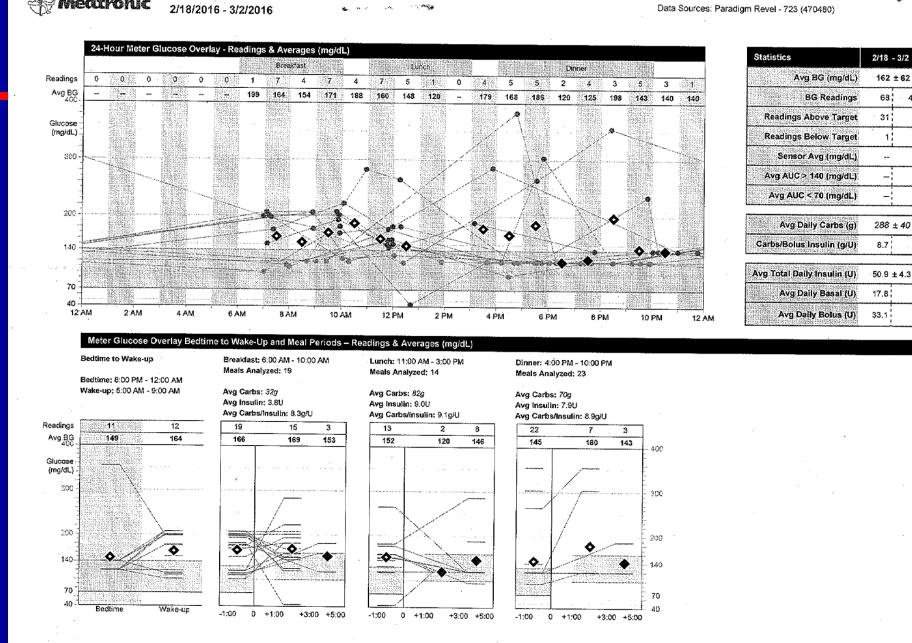
4.9/day

46%

1%

35%

65%



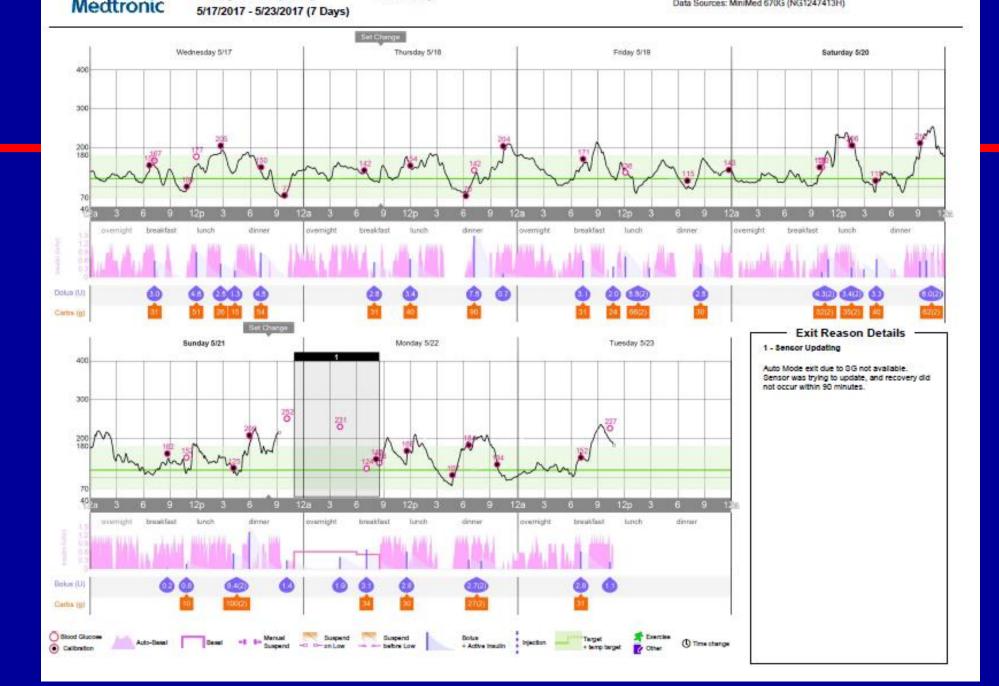
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— BG reading BG reading ▼▲ Off chart Average within target range Average outside target range

Sensor & Meter Overview (1 of 2)

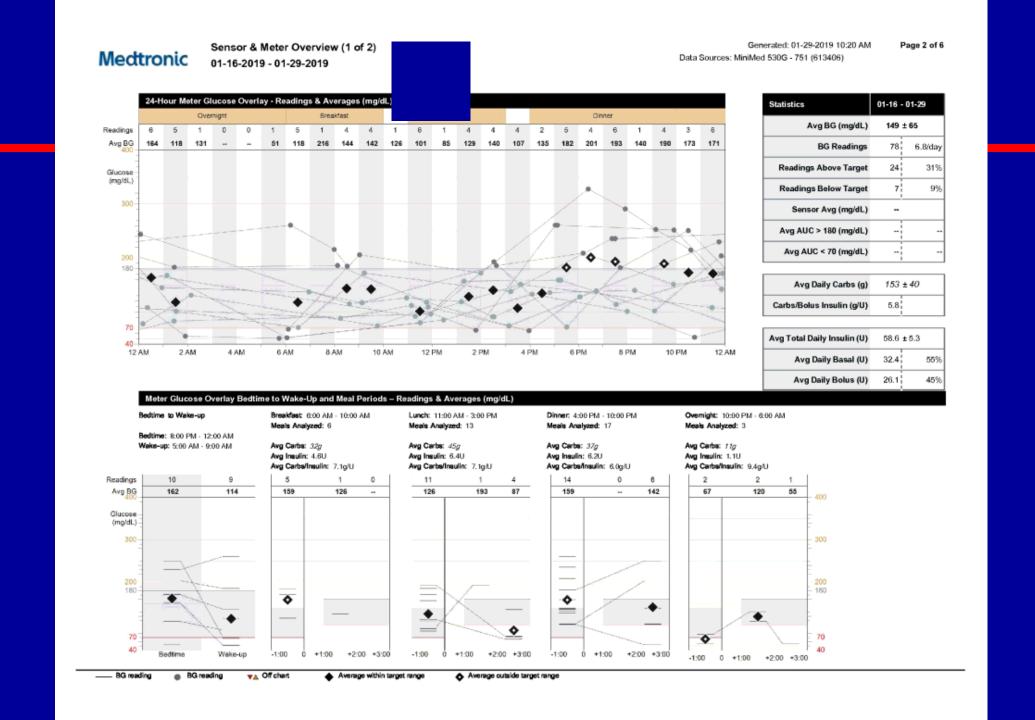
A Medironic

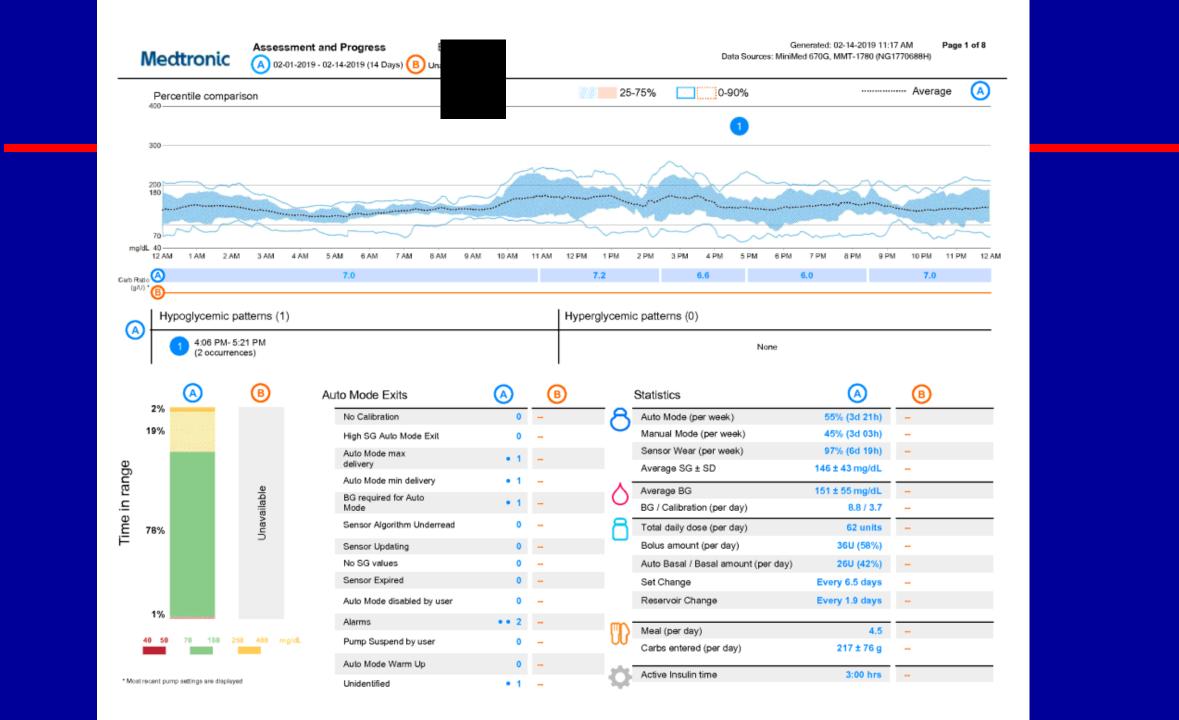


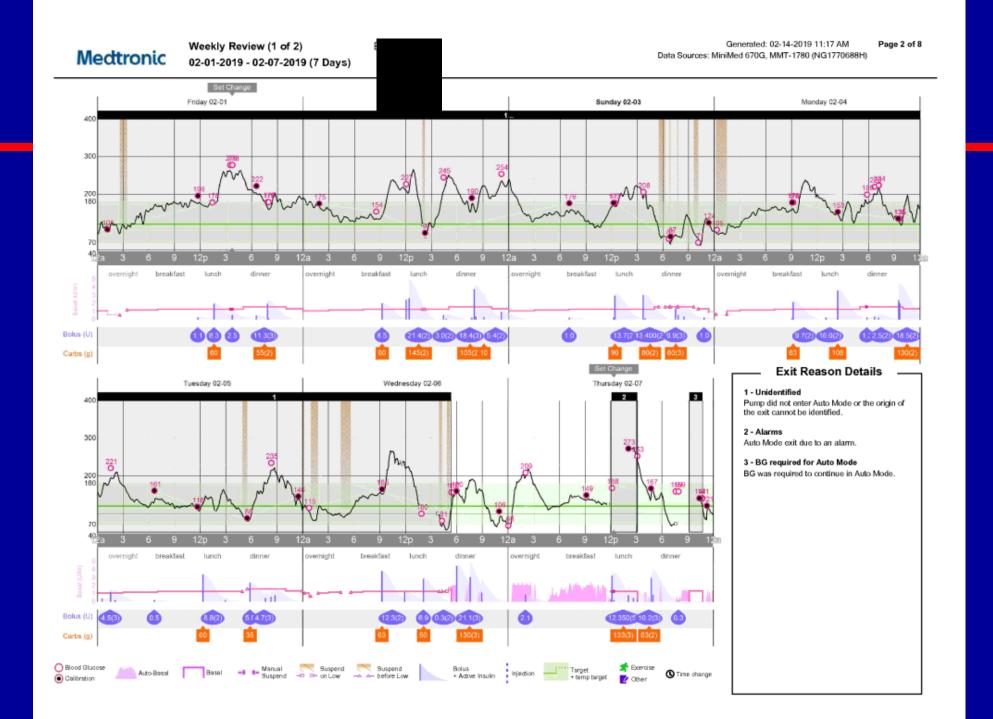




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80. G.				Auto Mode Exits No Calibration High SG Auto Mode Exit Auto Mode max delivery Auto Mode min delivery BG required for Auto Mode Sensor Algorithm Underread Sensor Updating No SG values Sensor Expired Auto Mode disabled by	0 0 0 0 0 0 0 1 0 0			Auto Mode (per week) Manual Mode (per week) Sensor Wear (per week) Average SG ± SD Estimated A1C Average BG BG / Calibration (per day) Total daily dose (per day) Bolus amount (per day) Auto Basal / Basal amount (per day)	94% (6d 14hrs) 6% (10hrs) 93% (6d 12hrs) 144 ± 34 mg/dL 6.6% 157 ± 41 mg/dL 5.7 / 4.0 26 units 14U (54%)	
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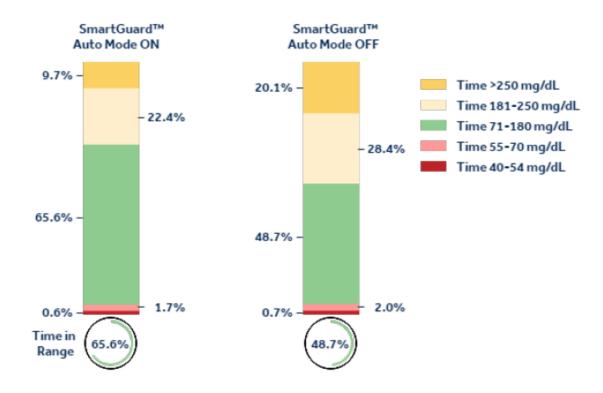




SENSOR GLUCOSE DISTRIBUTION: MINIMED™ 670G SYSTEM

Data Type: Healthcare Professional (BERNARD M DEGNAN)

U.S. MINIMED[™] SYSTEM DATASET* CareLink[™] Personal Data 41 Users Average Sensor Glucose (SG): 170.7 Time in Auto Mode: 62.9% Time in Range (Auto Mode): 65.6% PARAMETER VALUES Selected Age: All Ages Selected Dates: All Dates



* Only data from voluntary CareLink™ Personal or System uploads in the U.S. have been evaluated. Based on 2,212 days of data. Data collection began on March 2017.

** Time in range is the percentage of time glucose levels are between 70 - 180 mg/dL over a given period of time. Significant difference between SmartGuard™ feature on versus SmartGuard™ feature off (P < 0.05).

T-Slim X from Tandem





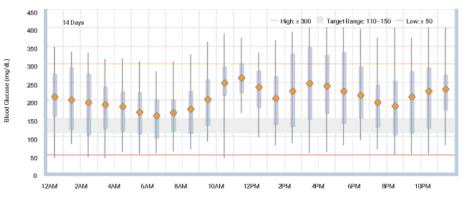


Born: Sun A

Report Printed

CGM Hourly | Aug 9 - 22, 2018

CGM Readings:
Above Target Average
Target Average
Below Target Average
Mid Range (25/75% - IQR)
Highest-Lowest Reading



Night12am - 6am	Morning 6am - 12pm	Afternoon 12pm - 6pm	Evening 6pm - 12am		
Low Below Target Above High	Low Below Target Above High	Low Below Target Above High	Low Below Target Above High		
Total Readings:	Total Readings:	Total Readings:	Total Readings:		
2% 21% 10% 56% 12%	0% 17% 9% 61% 12%	0% 10% 17% 47% 26%	0% 20% 11% 52% 17%		
Time in range (Avg)	Time in range (Avg)	Time in range (Avg)	Time in range (Avg)		
5 min. 1:07 hrs. 33 min. 2:58 hrs. 37 min.	1 min. 50 min. 27 min. 255 35 min.	- 29 min 49 min. 214 1:13 hrs. hrs. hrs.	- 1:01 hrs. 33 min. 2:44 hrs. 55 min.		
Avg. Glucose (mg/dL): 190	Avg. Glucose (mg/dL): 202	Avg. Glucose (mg/dL): 229	Avg. Glucose (mg/dL): 210		
Standard Deviation (mg/dL): 79	Standard Deviation (mg/dL): 80	Standard Deviation (mg/dL): 92	Standard Deviation (mg/dL): 94		
Avg. Readings Per Day 64	Avg. Readings Per Day 58	Avg. Readings Per Day 57	Avg. Readings Per Day 63		

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Bom: Sun Aug 13 2006 Age:

Report Printed on Thu Dec 06 2018

Therapy Timeline | Dec 4, 2018



The Omnipod : Dash and Horizon



The next step: Closed Loop

All pumps are developing "personalized" dietary dosing software for their hybrid pumps (4 years?) Internalization??



This stuff works!

- Continuous Glucose Monitoring Associated With Less Diabetes-Specific Emotional Distress and Lower A1c Among Adolescents With Type 1 Diabetes, Anthony T. Vesco, Aneta M. Jedraszko, Kimberly P. Garza, Jill Weissberg-Benchel, <u>J Diabetes Sci Technol.</u> 2018 Jul; 12(4): 792–799
- Metrics Beyond Hemoglobin A1C in Diabetes Management: Time in Range, Hypoglycemia, and Other Parameters, Lorena Alarcon-Casas Wright, MD, FACE and Irl B. Hirsch, MD, <u>Diabetes Technol Ther</u>. 2017 May 1; 19(Suppl 2): S-16–S-26
- Deiss et al, Improved Glycemic Control in Poorly Controlled Patients with Type 1 Diabetes Using Real-Time continuous Glucose Monitoring, <u>Diabetes Care</u> 2006 29: 2730-2732
- Bergenstal Et al. Effectiveness of Sensor Augmented Insulin pump Therapy. <u>NEJM</u> 2010
- Del Favero S, Boscari F, Messori M, et al. Randomized Summer Camp Crossover Trial in 5- to 9-Year-Old Children: Outpatient Wearable Artificial Pancreas Is Feasible and Safe. <u>Diabetes</u> <u>Care</u> 2016; 39:1180.
- Zabeen B, Craig ME, Virk SA, et al. Insulin Pump Therapy Is Associated with Lower Rates of Retinopathy and Peripheral Nerve Abnormality. <u>PLoS One</u> 2016; 11:e0153033.

Psychosocial Aspects of Type 1 Diabetes

Diabetes Care. 2007 Oct;30(10):2716-24. Epub 2007 Jul 20.

Routine psychological screening in youth with type 1 diabetes and their parents: a notion whose time has come?

Cameron FJ1, Northam EA, Ambler GR, Daneman D.

Pediatr Diabetes. 2009 Sep;10 Suppl 12:175-84. doi: 10.1111/j.1399-5448.2009.00580.x.

Psychological care of children and adolescents with diabetes.

Delamater AM1

School Performance and Type 1 Diabetes

Effect of type 1 diabetes on school performance in a dynamic world: new analysis exploring Swedish register data

Emma Persson, Sofie Persson, Ulf-G. Gerdtham, Katarina Steen Carlsson & for the Swedish Childhood Diabetes Study Group

Pages 2606-2622 | Published online: 23 Dec 2018

Download citation https://doi.org/10.1080/00036846.2018.1558347

ABSTRACT

This paper investigates if the effect of type 1 diabetes mellitus (T1DM) on school performance, documented in prior research, has changed in more recent birth cohorts of children using national Swedish population register data. The issue is of interest because management and treatment of the disease have improved over the last decades and, furthermore, because of changes in the educational grading system. Despite these changes, data indicate a persistent negative effect of T1DM on compulsory and upper secondary school grades with a standardized effect size of -0.109 and -0.070, respectively, and the results appear only marginally smaller compared to earlier findings in cohorts completing school under the previous grading system. Moreover, the results are consistent for alternative model specifications and econometric estimation strategies. Whereas access to new treatment technologies and improved diabetes management strategies has reduced the burden of diabetes in daily life, the results from this study indicate that continued efforts are needed to improve the situation in school for children with T1DM to prevent potential long-term socio-economic consequences.



• Insulin Pump:

- \$5-7,000 for the pump
- \$100-200 pre month for infusion sets
- Continuous glucose sensor:
 - Transmitter: \$240 (lasts 6-12 months)
 - Sensors: \$120 each (1 per week)

Libre

- Scanner: \$60-70
 - App available on I-Phones, can use as scanner
- Sensors: \$50 each (last 2 weeks)



PICU hospitalization for DKA: \$12,000 One year of renal dialysis: \$53,000

Access to care and technology

Future Topics (No time today...)

- Use of sensor / pump technology in hospital / procedures
- New onset: in or outpatient?
- Starting sensor and/or pump right away