# Troubleshooting Common Control Issues

John Walsh, PA, CDTC   Saturday, March 7, 2015

# Disclosure

- Book sales – all pump companies

- Advisory Boards – Companion Diabetes, Convatec, PicoLife Technologies

- Consultant – Bayer, Roche, BD, Abbott, Tandem Diabetes, Acon Laboratories, Companion Diabetes

- Speakers Bureau – Tandem Diabetes, Animas

- Sub-Investigator – Glaxo Smith Kline, Animas, Lilly, Sanofi-Aventis, Bayer, Medtronic, Biodel, Dexcom, Novo Nordisk, Halozyme

- Pump Trainer – Accu-Chek, Animas, Medtronic, Omnipod, Tandem

- Web Advertising – Sanofi-Aventis, Sooil, Tandem Diabetes Medtronic, Animas, Accu-Chek, Abbott, etc.

# Outline

- How to use CGM to troubleshoot control problems

- Troubleshooting the infusion set

- The Future
  - Better connectivity and analysis
  - Replace fingersticks
  - Control via the closed loop (or variations of)

# CGM Usage from T1 Exchange data

☐ **Enrollment (6% use CGM overall)**

■ **Current (9% use CGM overall)**



c. 2013
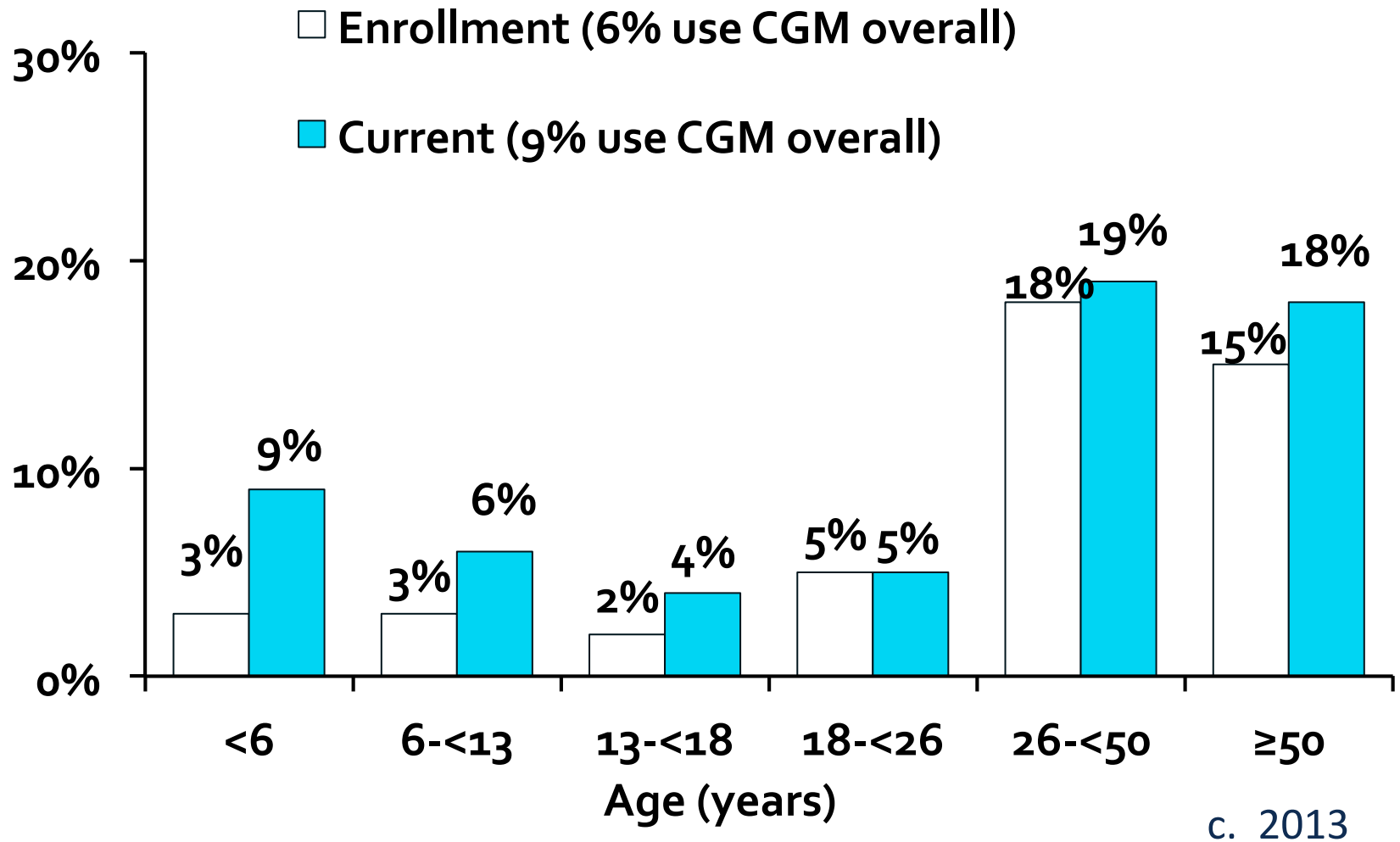
In early 2014, we surveyed 502 US pumpers – 79% had experience (short or long) with a CGM and 59% currently wore one.

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# CGM Calibration Tips

- Use an accurate meter

- Use good technique – clean fingers, no expired strips, enter reading right away

- Calibrate when CGM requests this and anytime that fingerstick varies from CGM reading (and consider whether to retest fingerstick)

- Do more calibrations on first day of use

- Calibrate at the extremes (when low and when high)

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# CGM Screen Information

- **Glucose value** – updated every 5 min

- **Trend line** – direction of glucose change

- **Trend arrow** – rate of change (ROC)

- **Alerts**

  - High and low threshold

  - Predictive

  - Rate-of-change



Trend Line  Trend Arrow

3 hr

144

Glucose Value

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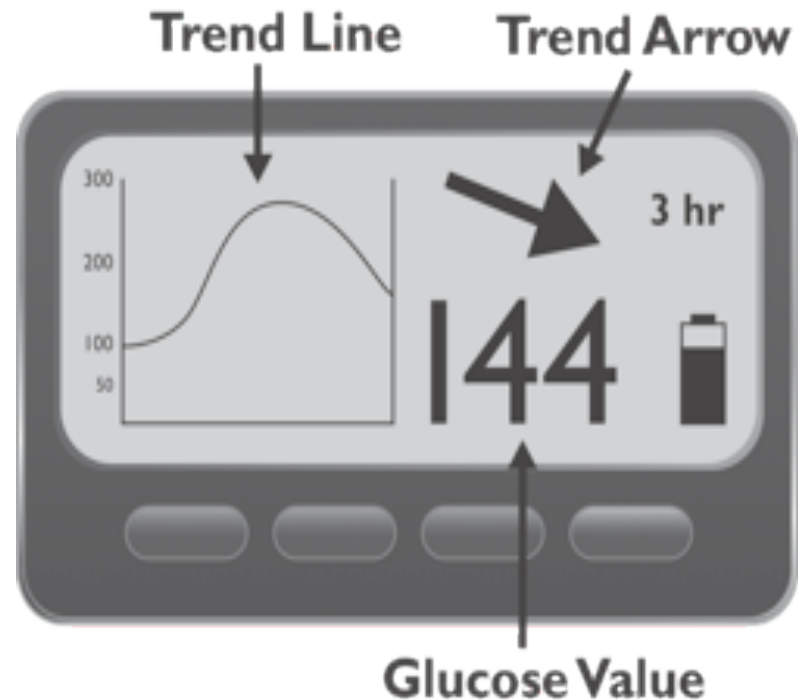
# Trends Arrows (mg/dL/hour)

| Arrow | Dexcom | Medtronic |
| --- | --- | --- |
| ⬆⬆ | Rise **> 180 mg/dl/hour** | Rise **> 120 mg/dl/hour** |
| ⬆ | Rise = **120 to 180** | Rise = **60 to 120** |
| ↗ | Rise = **60 to 120** | (n/a) |
| ➡ | < 60 rise or fall (**stable**) | (n/a) |
| ↘ | Fall = **60 to 120** | (n/a) |
| ⬇ | Fall = **120 to 180** | Fall = **60 to 120** |
| ⬇⬇ | Fall **> 180** | Fall **> 120** |

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# Where To Set Alerts

**LOW:**       **80 mg/dl**  to start

Higher for young children and high risk jobs

**HIGH:**      **200 mg/dL)** based on current BGs

Gradually lower to 160 or 140 as control improves

The lower the high alert is, the earlier
the wearer knows their BG is rising

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

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# Adjust Insulin for BG, Trend, & BOB*

- BG Stable:  Usual Dose

- BG Rising Gradually:
  ⬆ bolus 10%

- BG Rising Sharply:
  ⬆⬆ bolus 20% (140%)

- BG Dropping Gradually:
  ⬇ bolus 10%

- BG Dropping Sharply:
  ⬇⬇ bolus 20%

*BOB = bolus [insulin] on board

# CGM Tips

- **Wear** the CGM at least 90% of the time and **look at the monitor** 10-20 times per day

- Look at trend lines not just individual BGs!

- Don't over-react – avoid frequent corrections until pattern is clear

- A rapid rise usually means more insulin needed, BUT check BOB first!

- Lag times (usually 5-8 min) are longest after you treat a low glucose
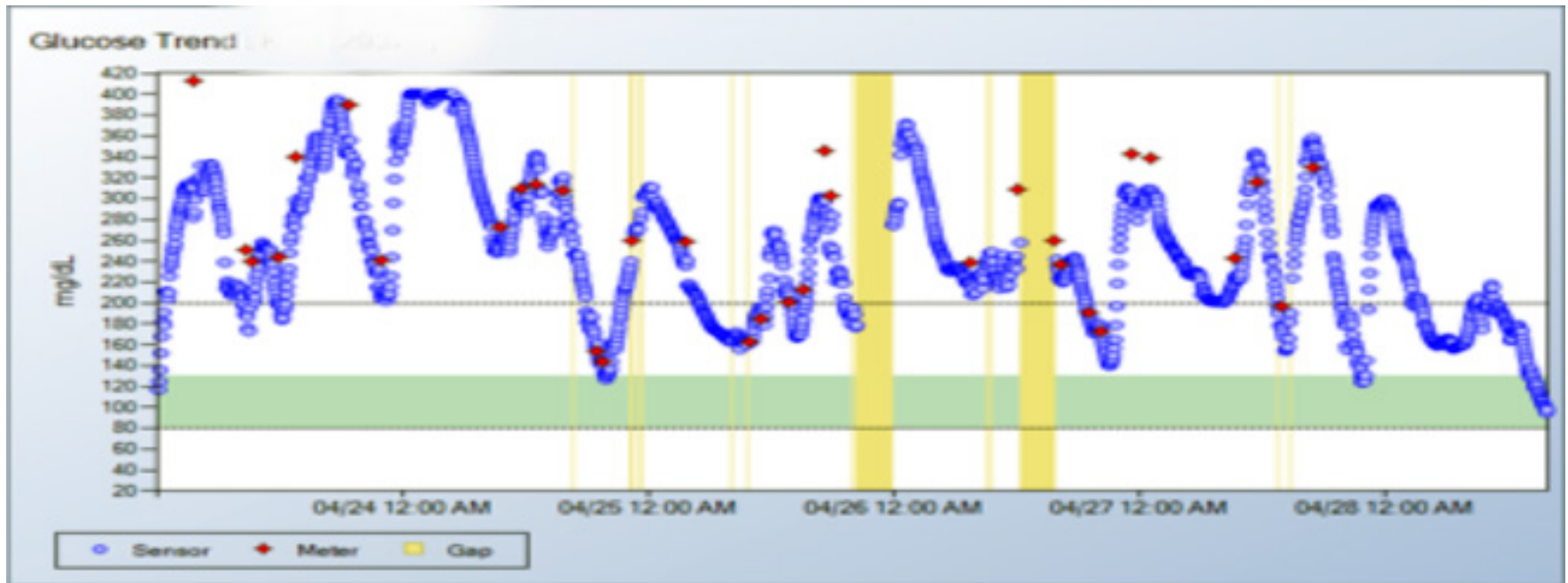
# Glucose Profile – No Diabetes
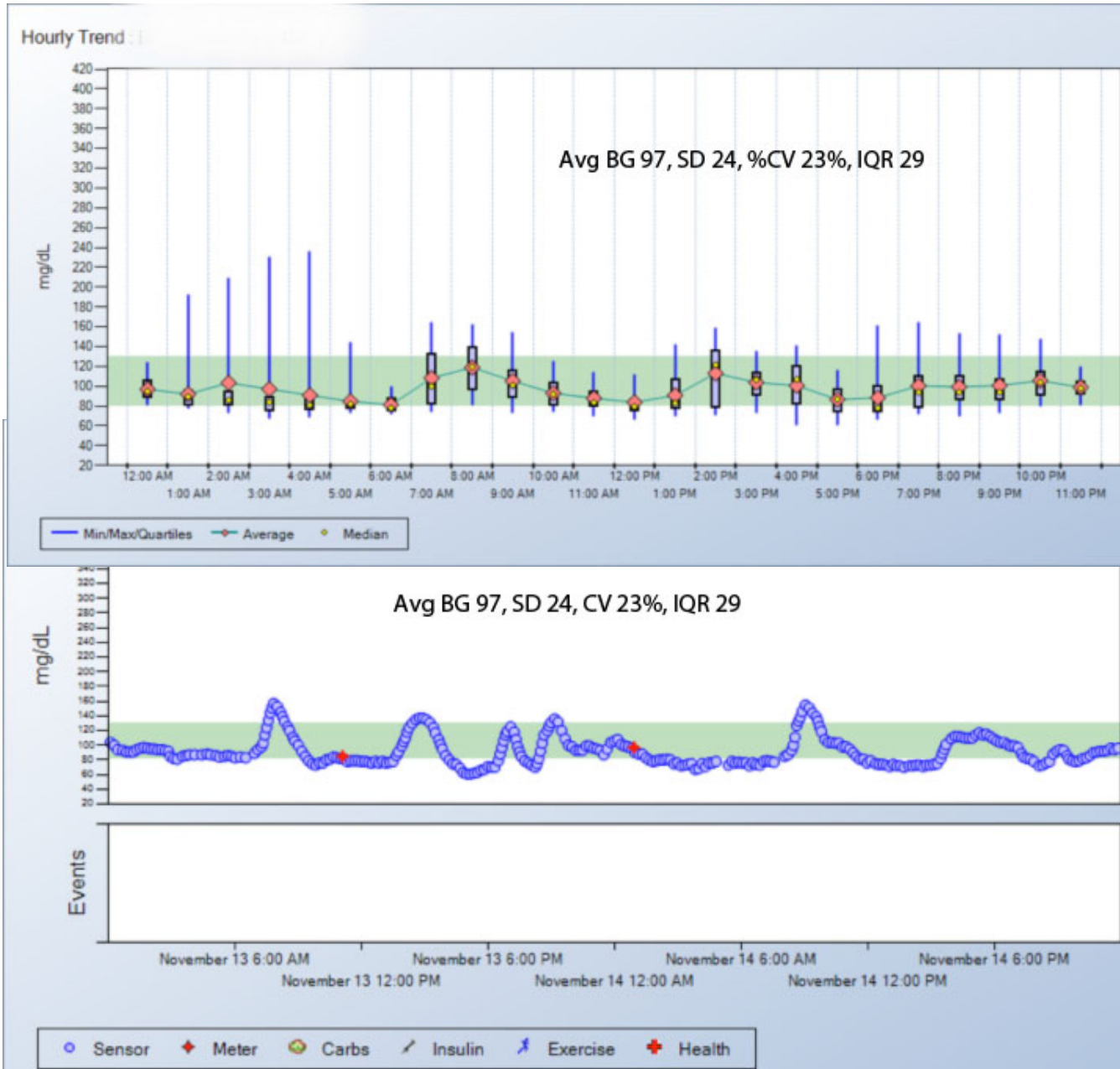
# Glucose Profile – Poor Control
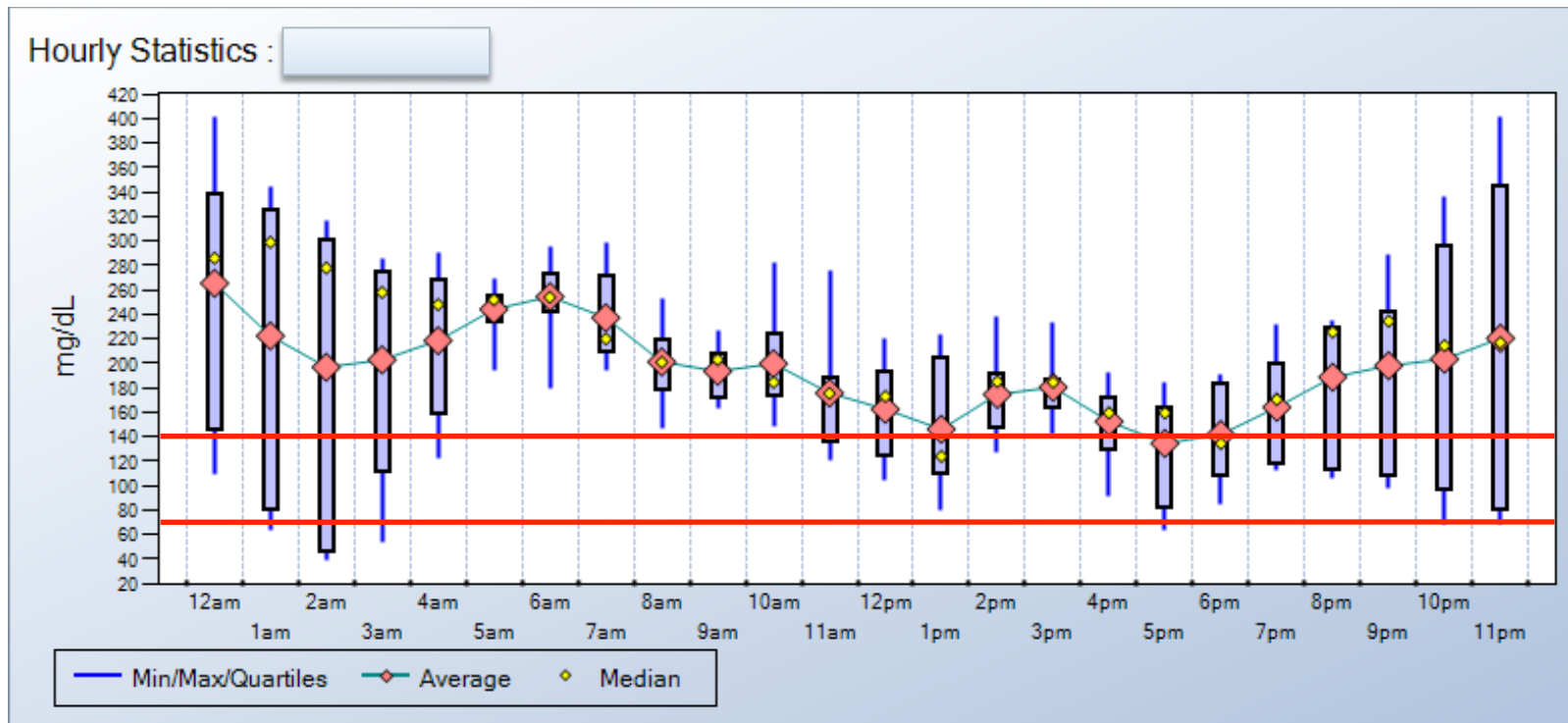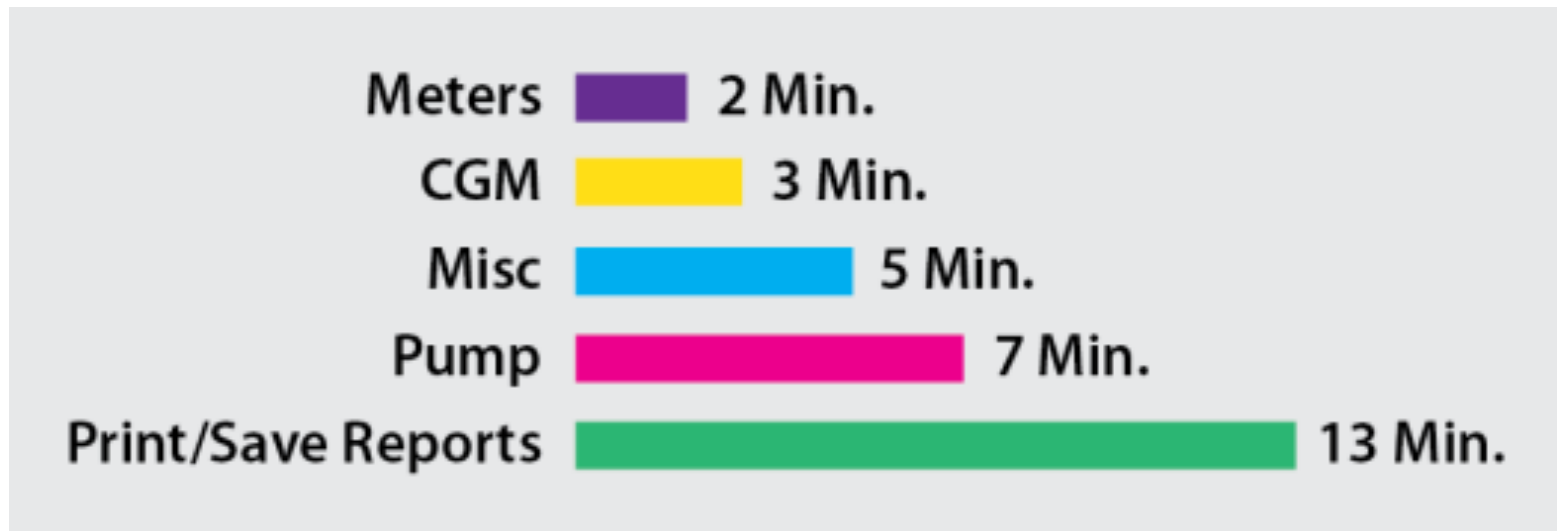


**Comes in *many* variations!**

# Downloads Help Your Health Care Provider – So Bring Meaningful Data



"Pumping gas and brakes"

- Look for repeat patterns – correct patterns rather than reacting and making same mistake over and over again

# Why People Don't Download



| | |
|---|---|
| Meters | 2 Min. |
| CGM | 3 Min. |
| Misc | 5 Min. |
| Pump | 7 Min. |
| Print/Save Reports | 13 Min. |

Takes 30 min or more to download data for doctor visit.

Thanks to Laddie at http://testguessandgo.com/tag/dexcom/

# Jackson Pollack's CGM Tracing



Price: $3,000,000

# What CGM Information is Used?

Of 222 survey respondents with Type 1 diabetes:

- 51% rated trend line/trend arrow as most important

- 30% rated low and high glucose alerts as most important

- 15% thought real-time and download information were important

- **Only 3.6% reported that finding patterns from downloads was helpful**

40% never download and 17% report doing so only rarely

J Pettus, DA Price, SV Edelman. How patients with Type 1 diabetes translate continuous glucose monitoring data into diabetes management decisions. DOI: 10.4158/EP14520.OR © 2015 AACE.

# CGM Data – Trends vs Downloads
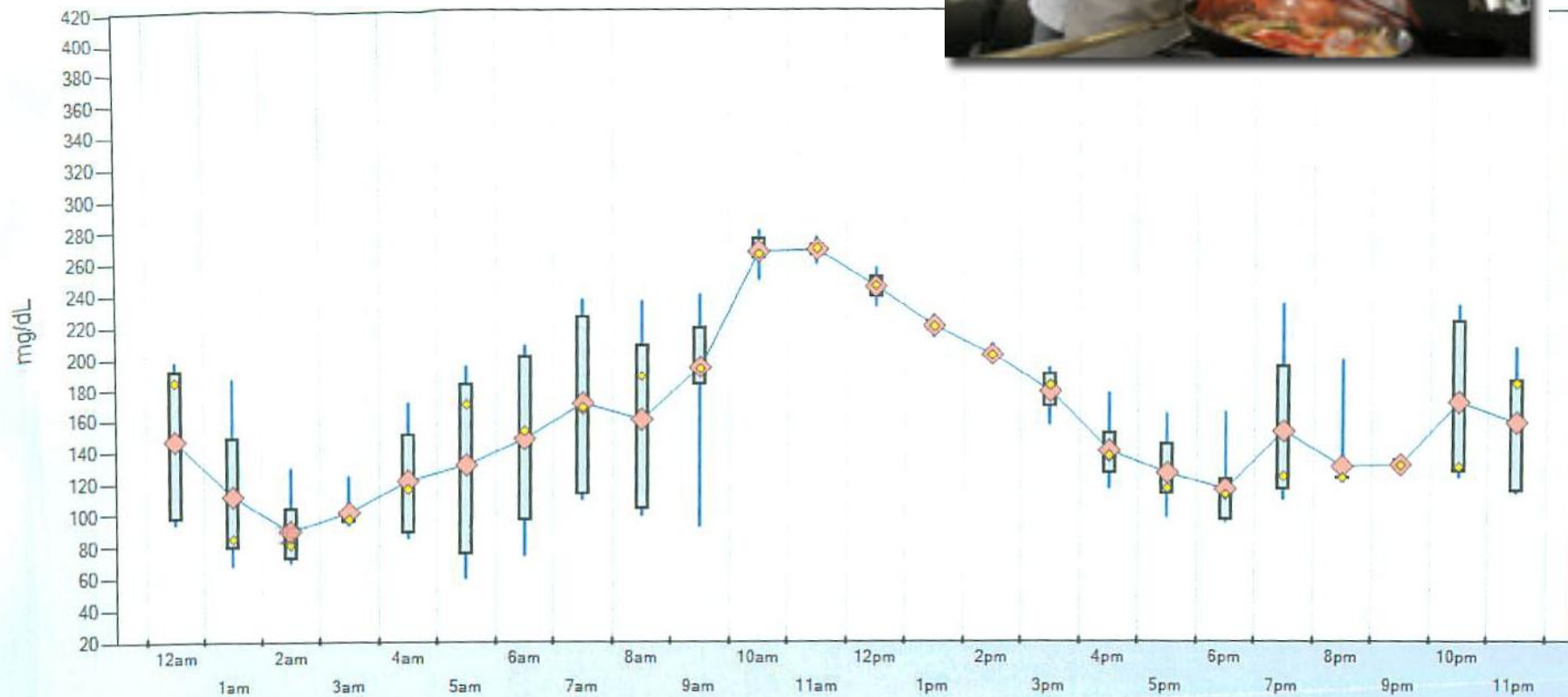
**RT Trendlines show:**

- Last 1-24 hrs readings
- One night's basal profile
- Profile of one meal
- A limited picture

**Downloaded data shows:**

- Multiple days' readings
- Frequent highs
- Frequent lows
- Roller-coaster readings
- Post-meal spiking
- A complete picture
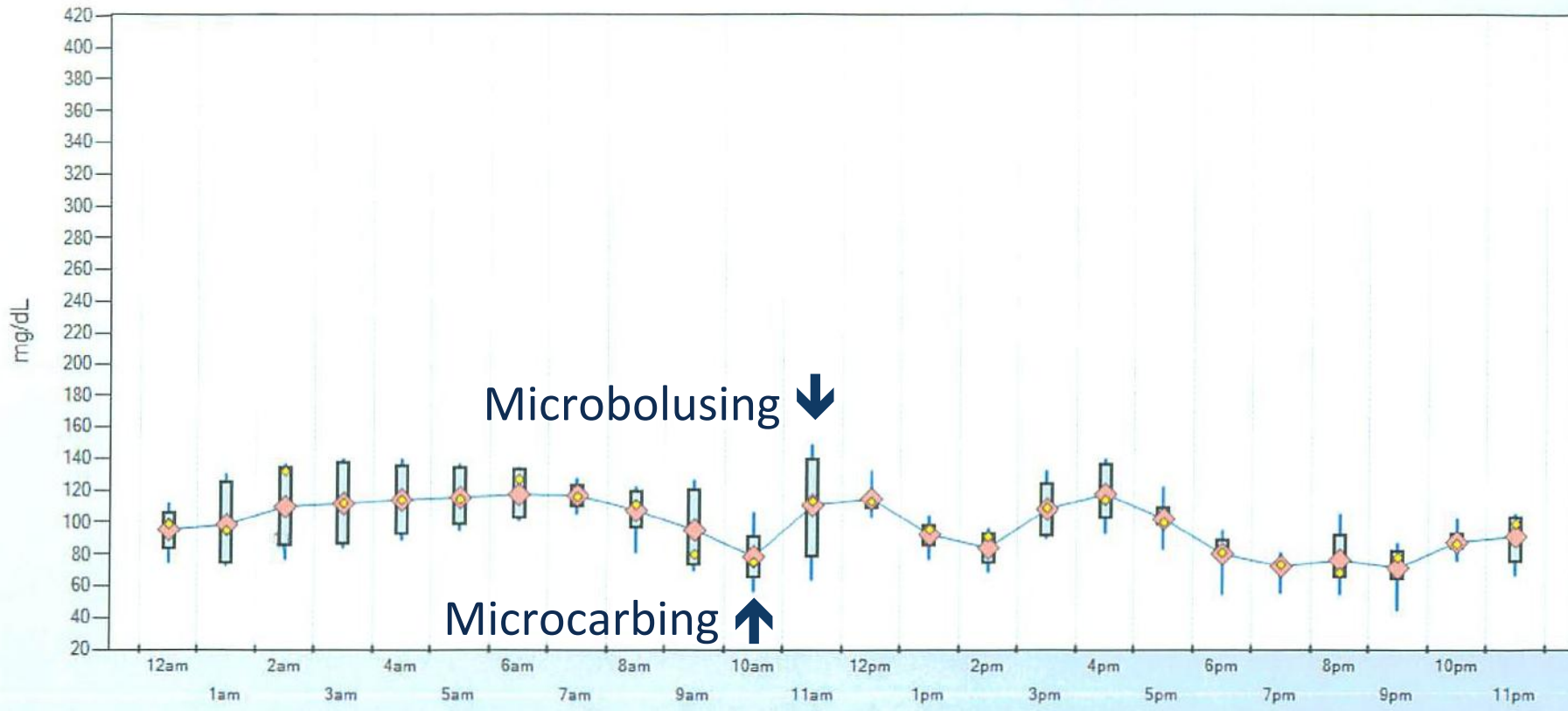
# Adjust from Trendlines
## First 2 Days (Download)
### Type 1 Chef (DM x 13 yr, c-peptide <0.5)



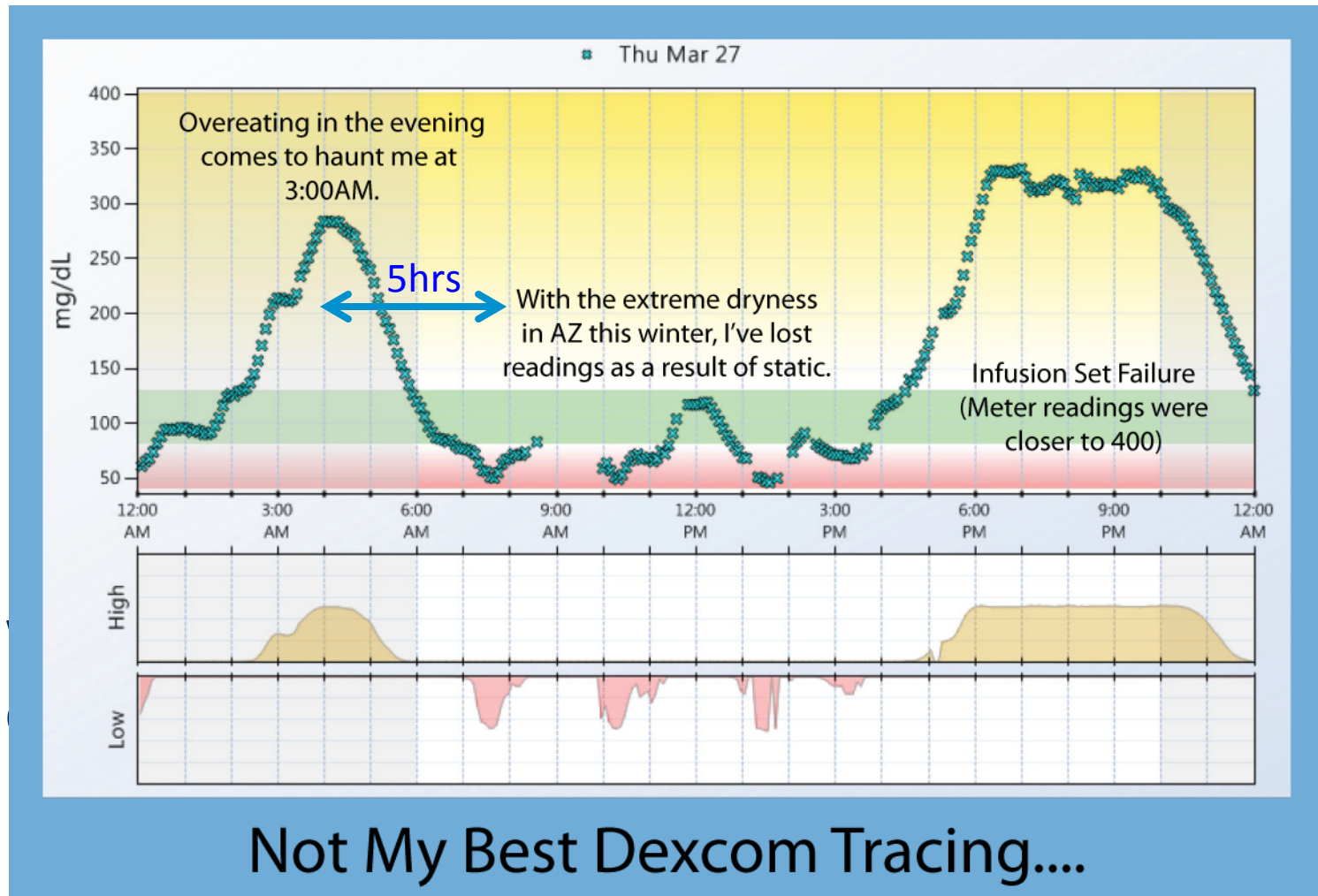CGM as a Behavior Modification Tool

# Adjust from Trendlines
# CGM Tracing – Following 2 Days



CGM as a Behavior Modification Tool

# Honesty Improves Downloaded Data



Thanks to Laddie at http://testguessandgo.com/tag/dexcom/

# Woman on Pump – 1ˢᵗ Visit



Glucose Trend : HM

Avg BG 205, SD 118, CV 58%, IQR 204

# Woman on Pump – 1st Visit



Glucose Trend : HM

Avg BG 205, SD 118, CV 58%, IQR 204

Hourly Trend : HM

Avg BG 205, SD118, %CV 58%, IQR 204
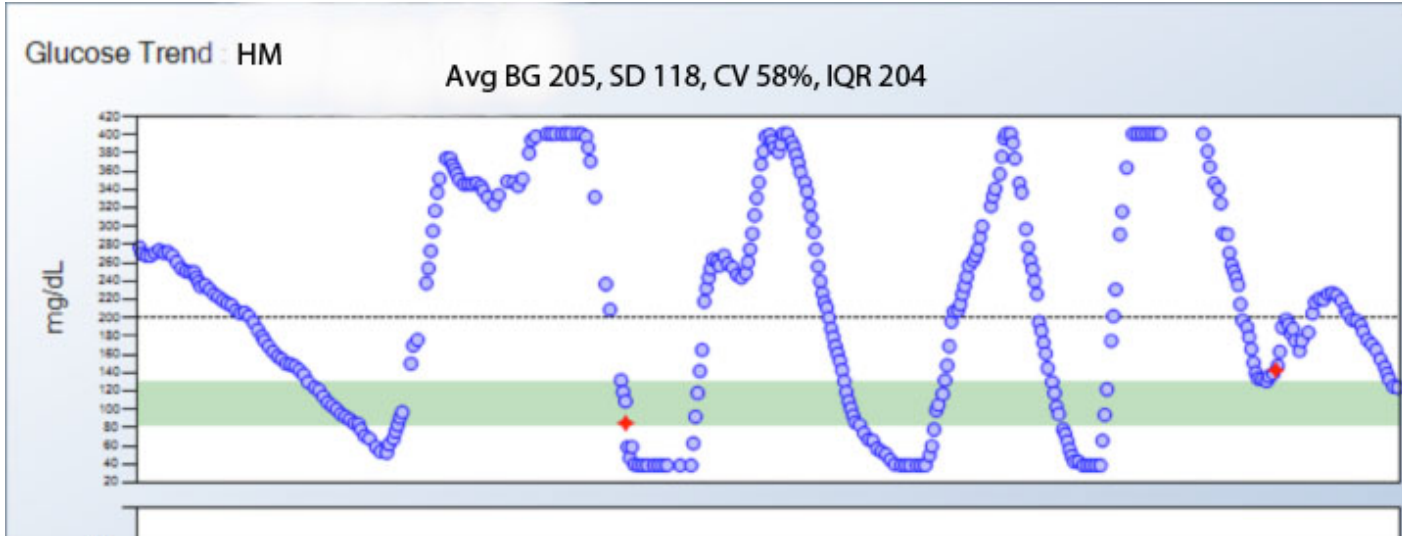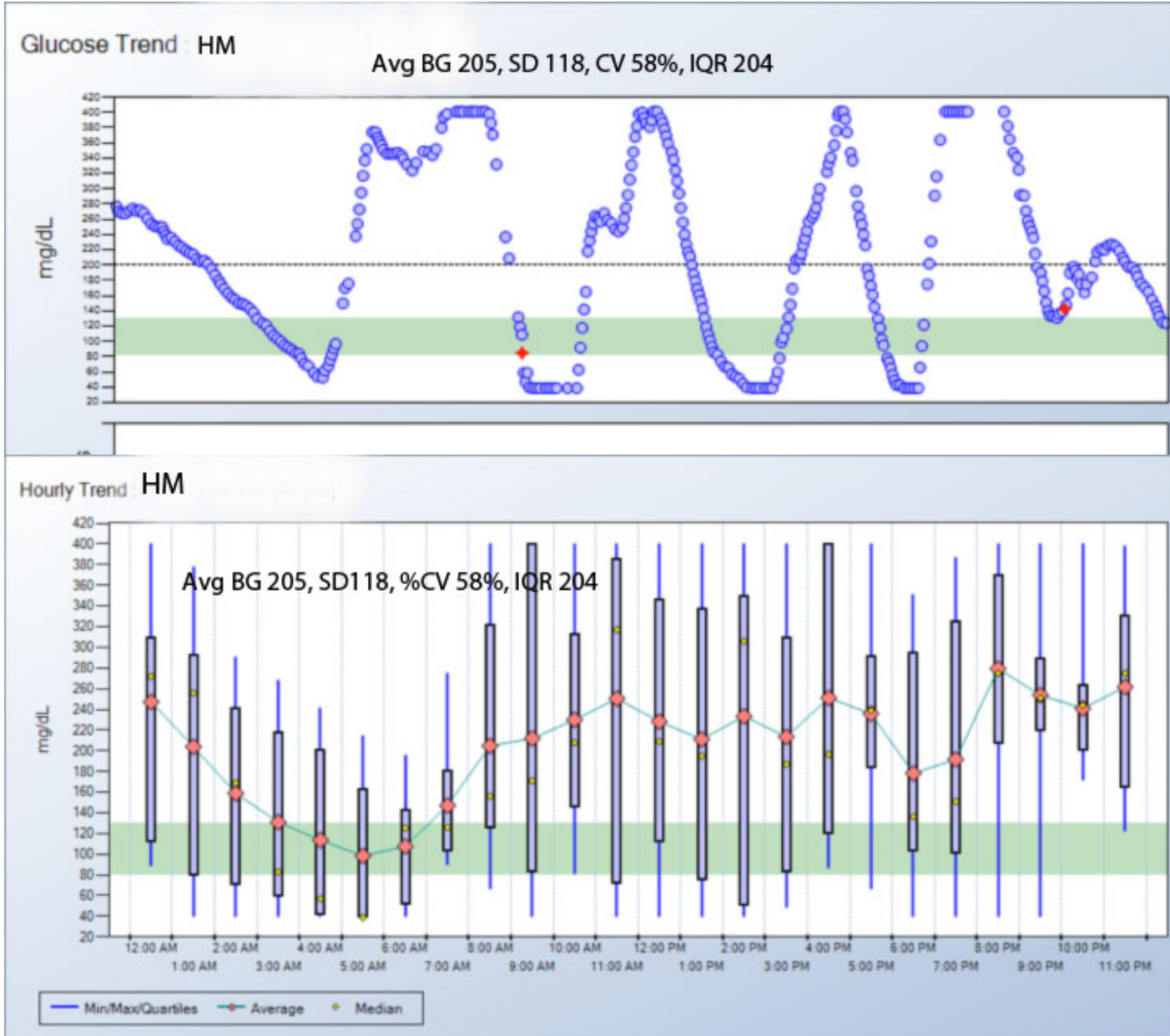
# Woman on Pump – 2ⁿᵈ Visit
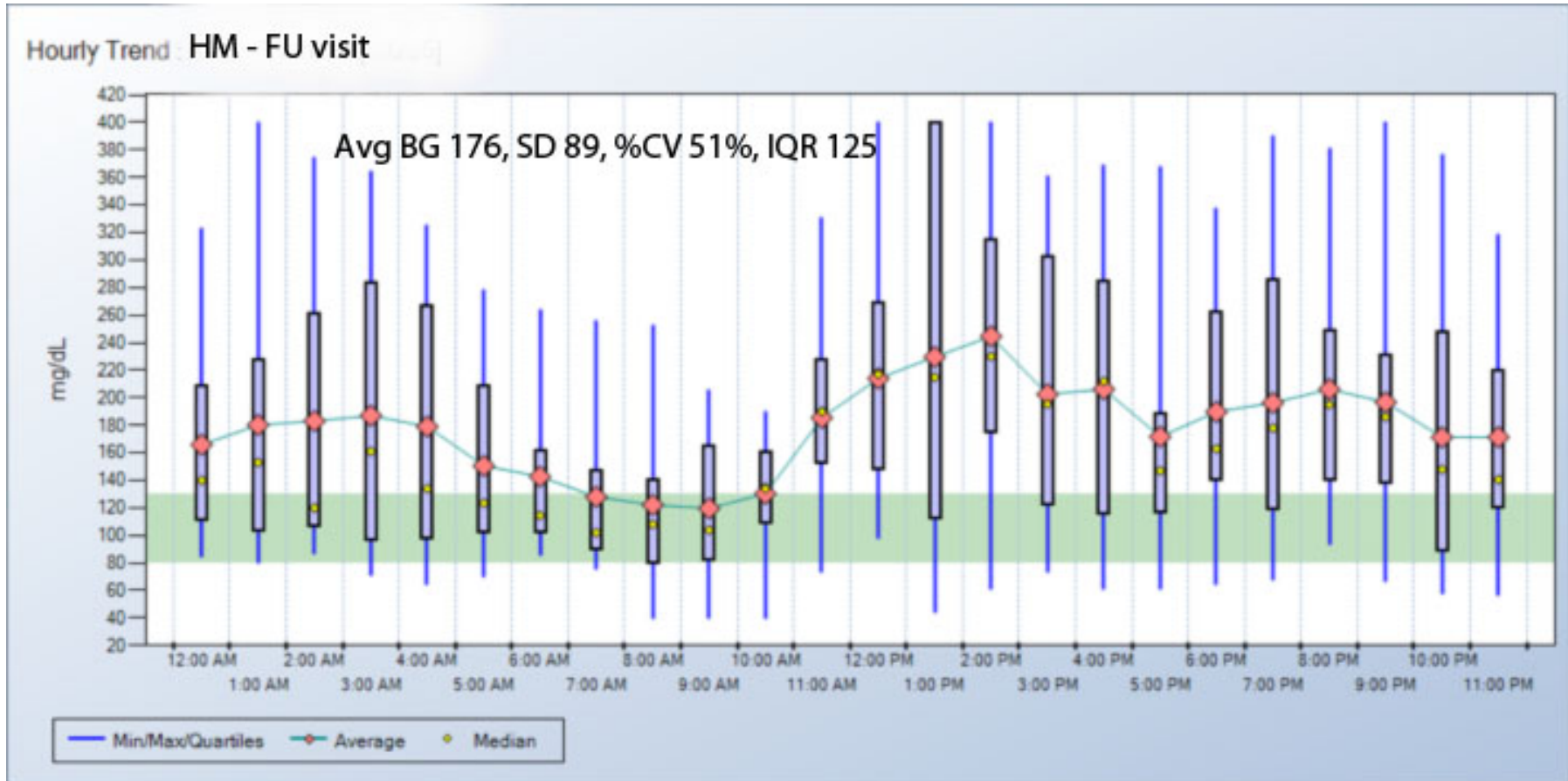
# How To Optimize Insulin

# Optimize Insulin Doses In Sequence

1. Correct frequent lows first
2. Then correct high A1c/avg BG

This lets you find
an ideal TDD (iTDD)

3. Set & test basals from iTDD   Keep overnight readings level

4. Set & test CarbF from iTDD   Fine-tune premeal BGs

5. Lower post meal BG's          Bolus early, low GI foods,
                                 add Symlin, GLP-1 agonist, etc

6. Set & test CorrF from iTDD    Brings highs down safely

7. Enjoy good control or return to #1

Brittle diabetes or frequent highs?
Usually = the wrong pump settings
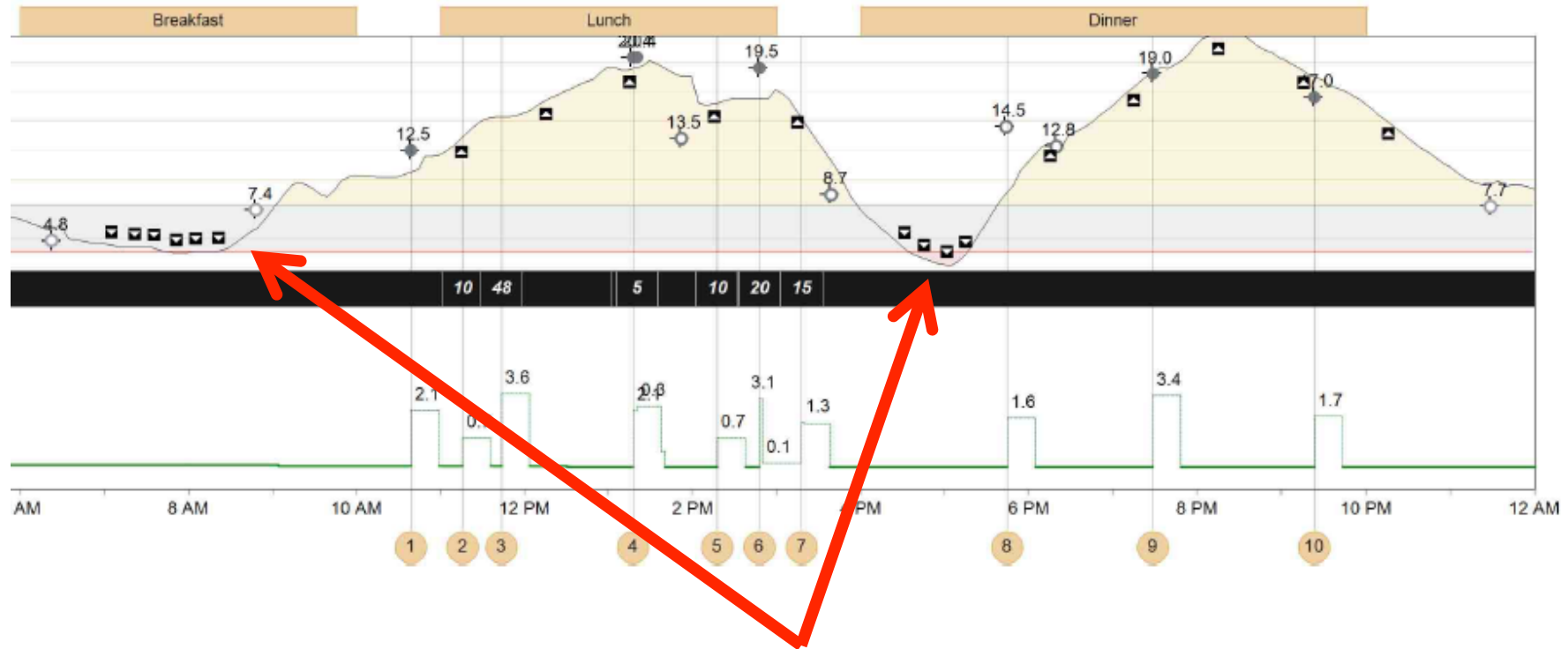
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# Incidence Rate* of SH at various ages
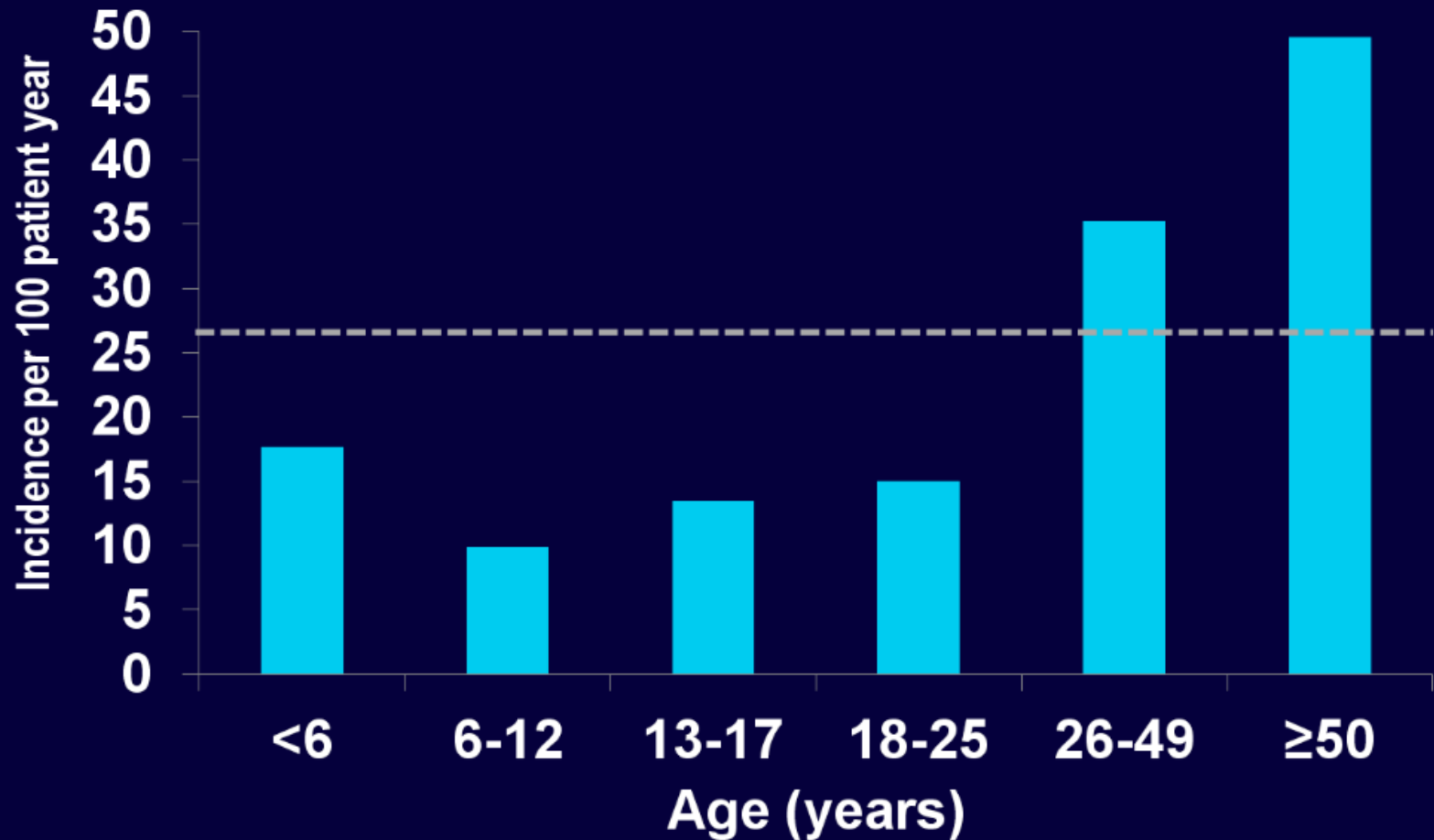
* the rate of seizure/coma in the DCCT was 26.7 /100 patient year
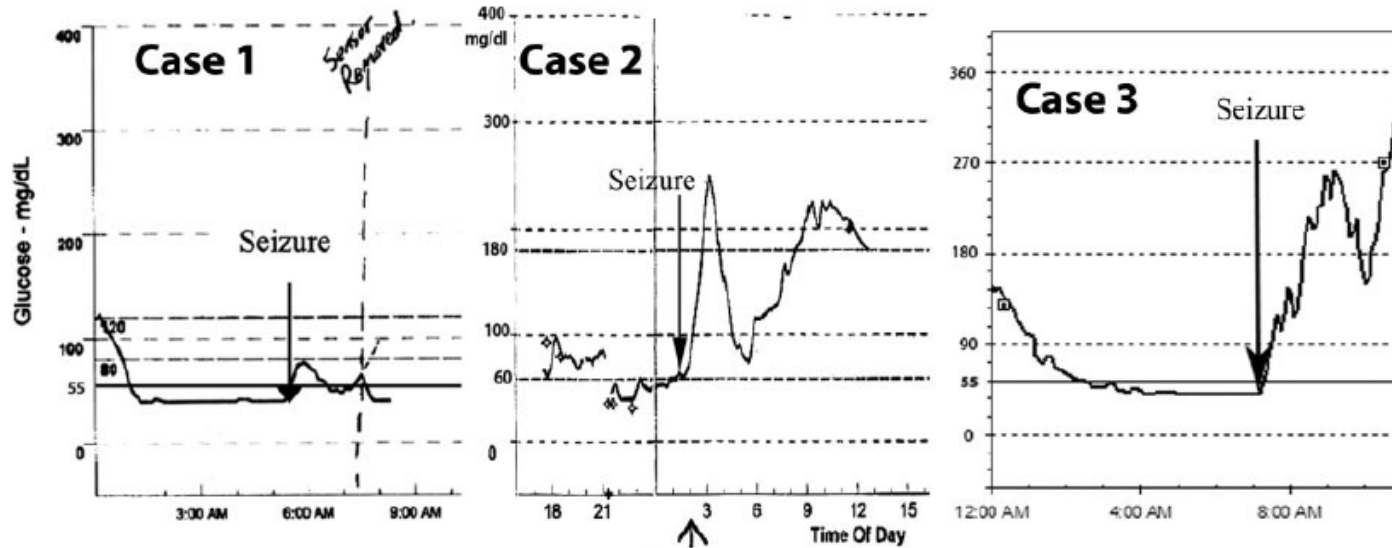
# Hidden Hypoglycemia



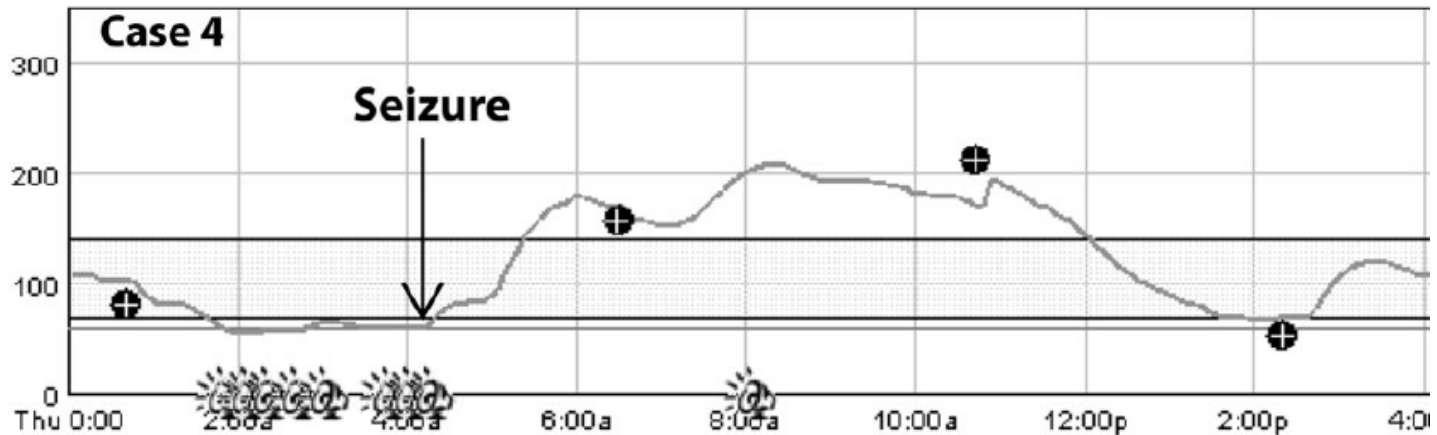He/She ate when low but never tested with a meter.
*Only a CGM sees this!*

# Nocturnal Hypoglycemic Seizures

# Stop Frequent Lows First

- **You cannot tell how much excess insulin there is!**

- Start with a 5% or 10% reduction in TDD

- Compare the current TDD to an "ideal" TDD for weight.

- Divide weight(lbs) by 4 to see what TDD would be used with an average sensitivity to insulin

**Example:** Someone who weighs 160 lbs would be expected to have a TDD of 40 units (160/4 = 40).

# Example 1 – Frequent Lows on Meter
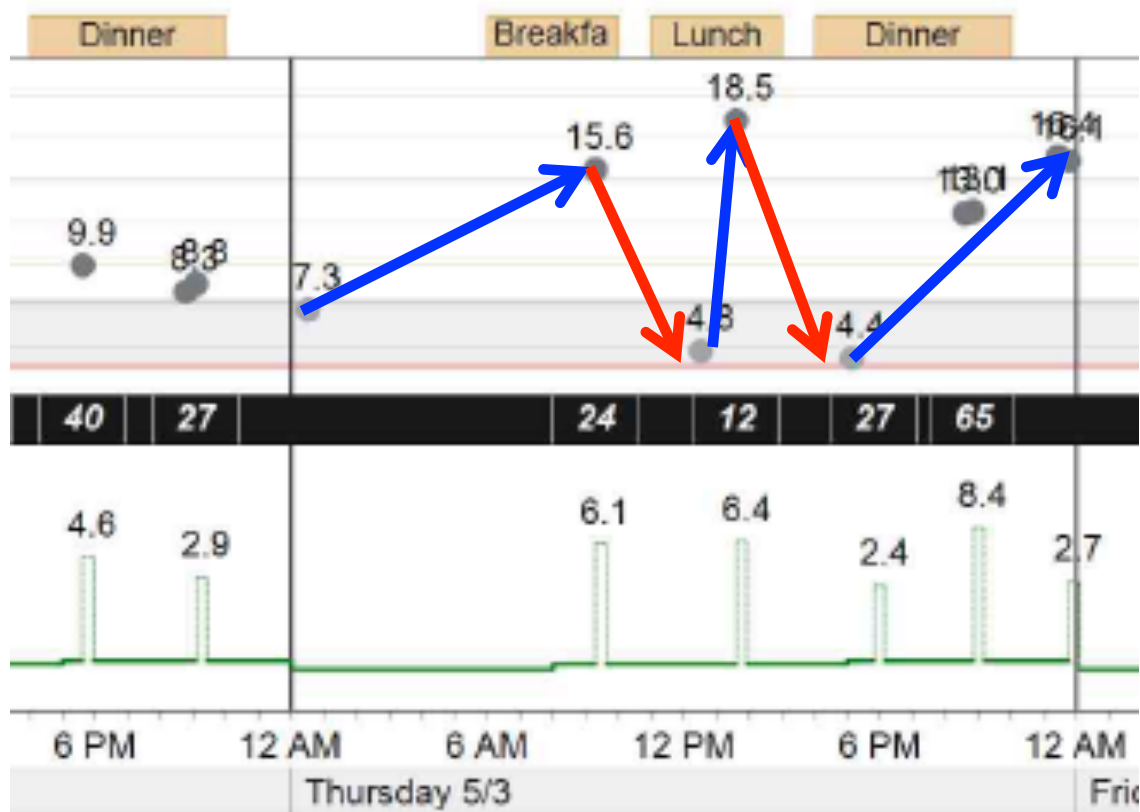


41 yo female with A1c = 6.9%

TDD = 50.5 u/d

152 lb/4 = 38.0 u/d

# Example 2 – Frequent Lows on CGM



**~ 2 Lows-to-Highs per day**

**70 mg/dl**

28 yo female – Wt: 120 lbs

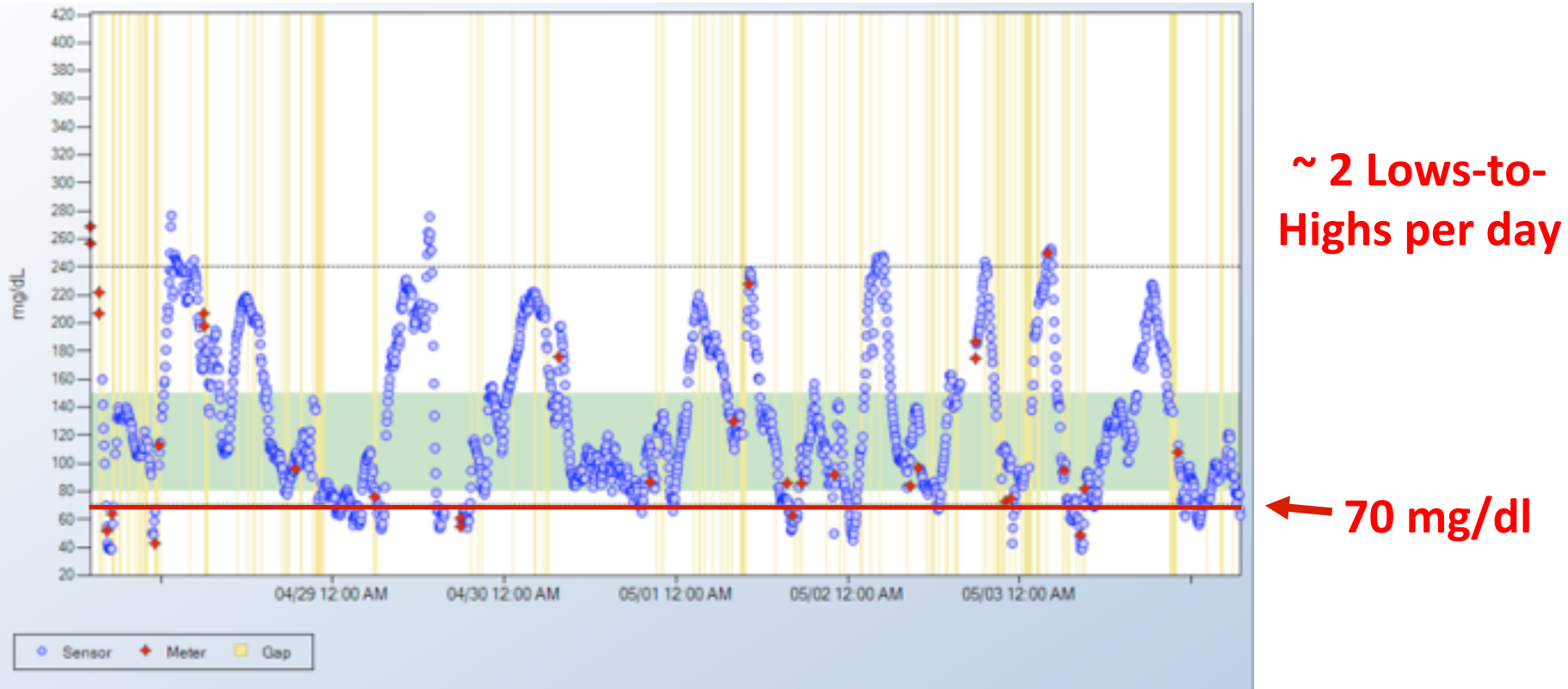Current TDD  =    43.6 u/day

Wt/4 (120/4) =    30.0 u/day

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# Then Stop Frequent Highs

**Raise TDD:**

**by 1% to lower average BG by 6 mg/dL**

**or by 5% to lower A1c by 1%**

$$\frac{\text{Current BG} - \text{Target BG}}{6} = \text{\% rise in TDD}$$

**Example:** Amy's avg TDD is 40 u/day, avg BG 200 mg/dL (few lows), and BG goal 140 mg/dL:

200 mg/dL  –  140 mg/dL  =  60 mg/dL

60 mg/dL ÷ 6 =  10% rise in TDD

40 units  x  1.10  =  44 units a day

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# Example 1 – Lower Highs from A1c
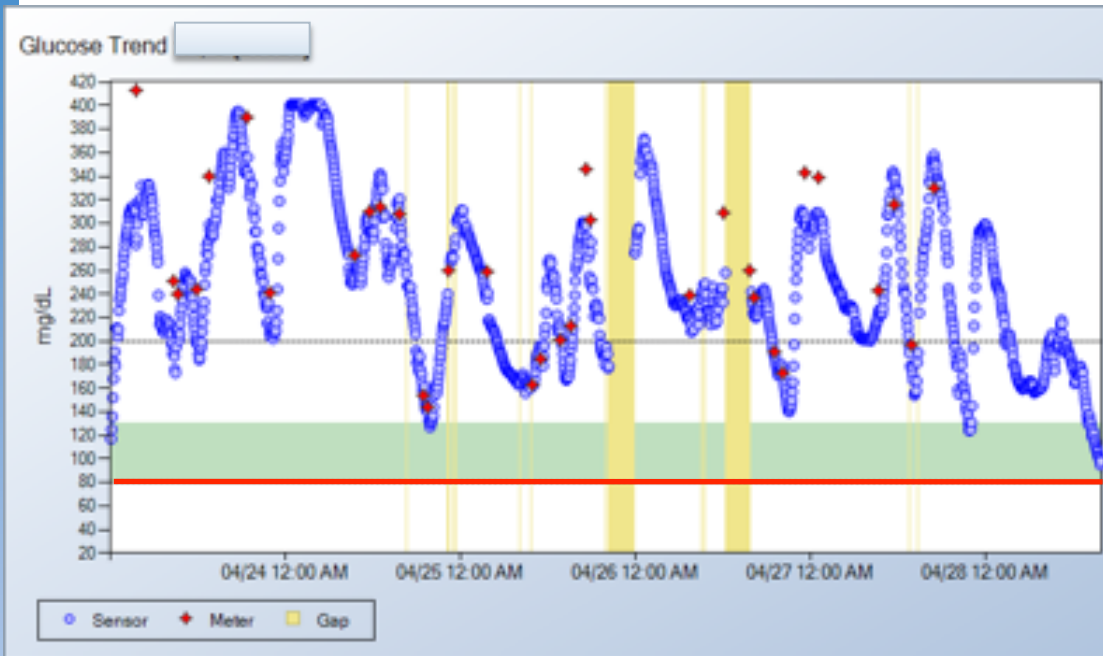


27 yo male, A1c = 8.6%, TDD = 50 u/day

8.6% - 7.0% = 1.6% x 5 = an 8% increase in TDD

50u x 1.08 = 54u

Bring downloads to your HCP so they can help you interpret them yourself!



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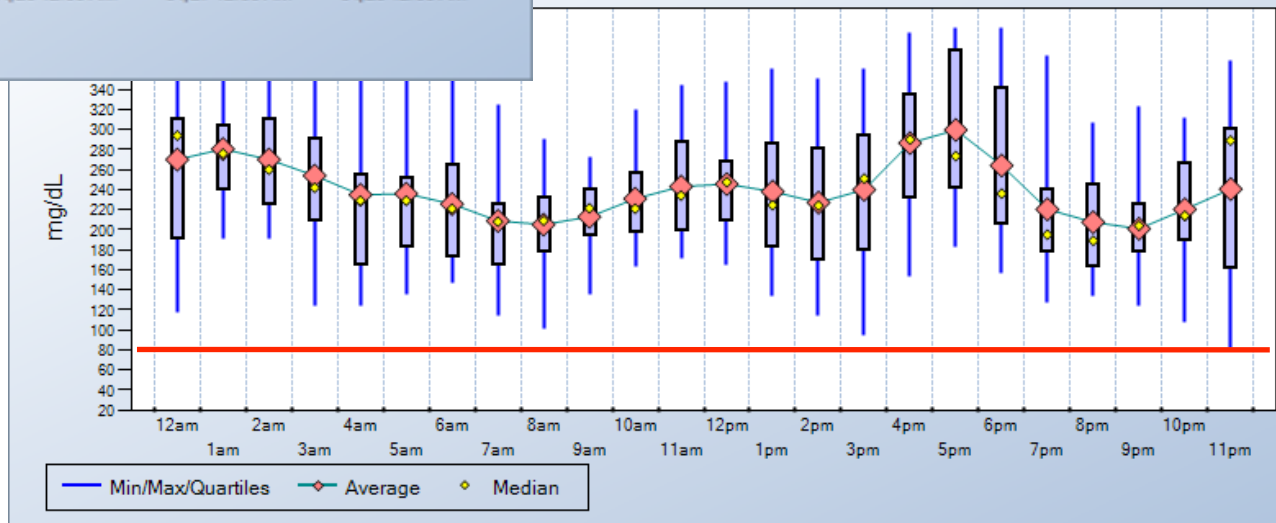
# Example 2 – Lower Highs from Avg BG



**1** Low basal

**2** Too little carb bolus

Hourly Statistics :

Min/Max/Quartiles — Average — Median
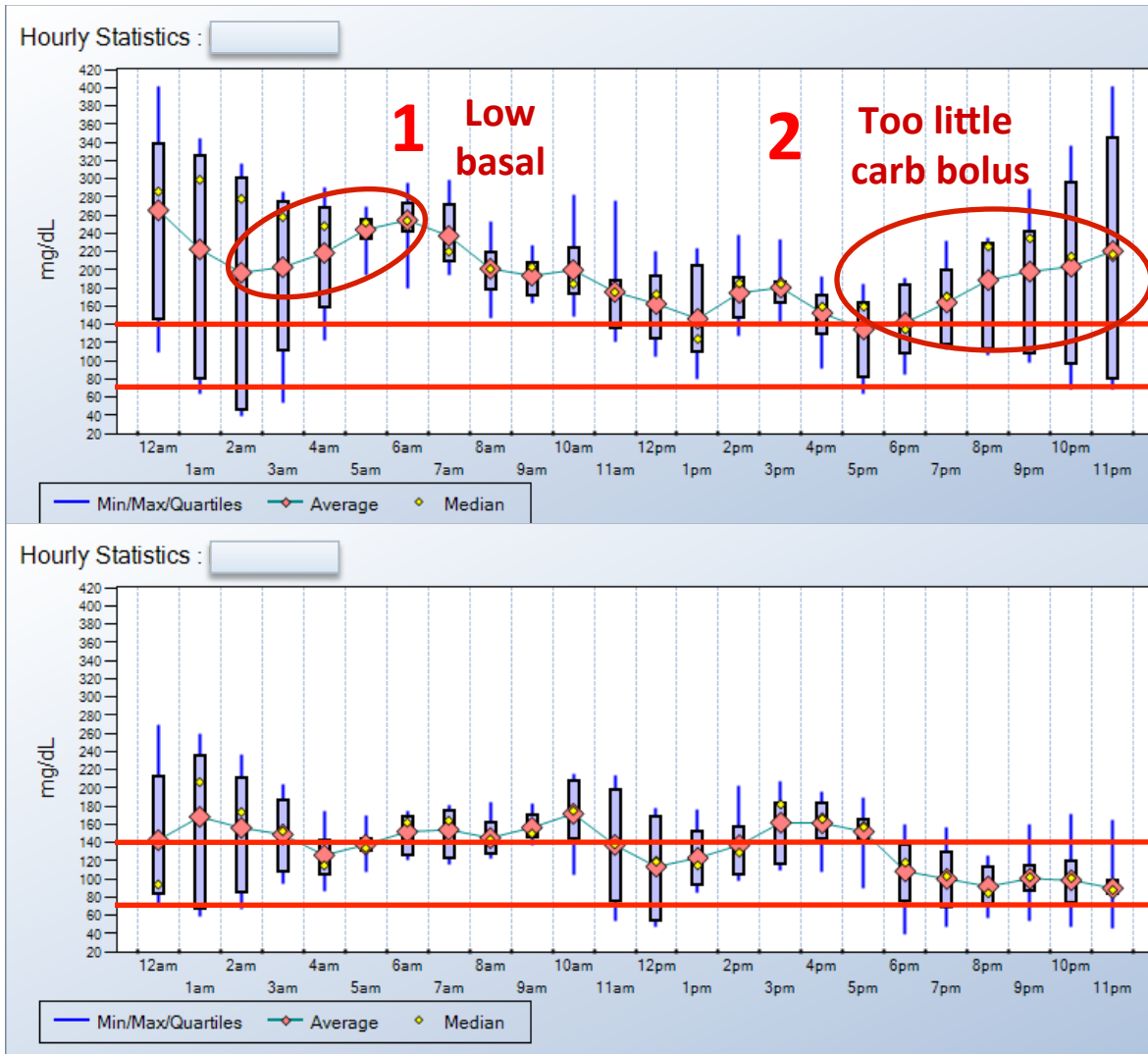
**53 yo female**
**TDD = 36 u**
**Avg BG = 191**

o Raise basal by 0.05 u/hr all day (+1.2 u/day)

o Lower CarbF from 1u/13g to 1u/12g (+1.8 u/day)

**TDD = 39 u**
**8.3% increase**

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# T1 DM on the "Rollercoaster"
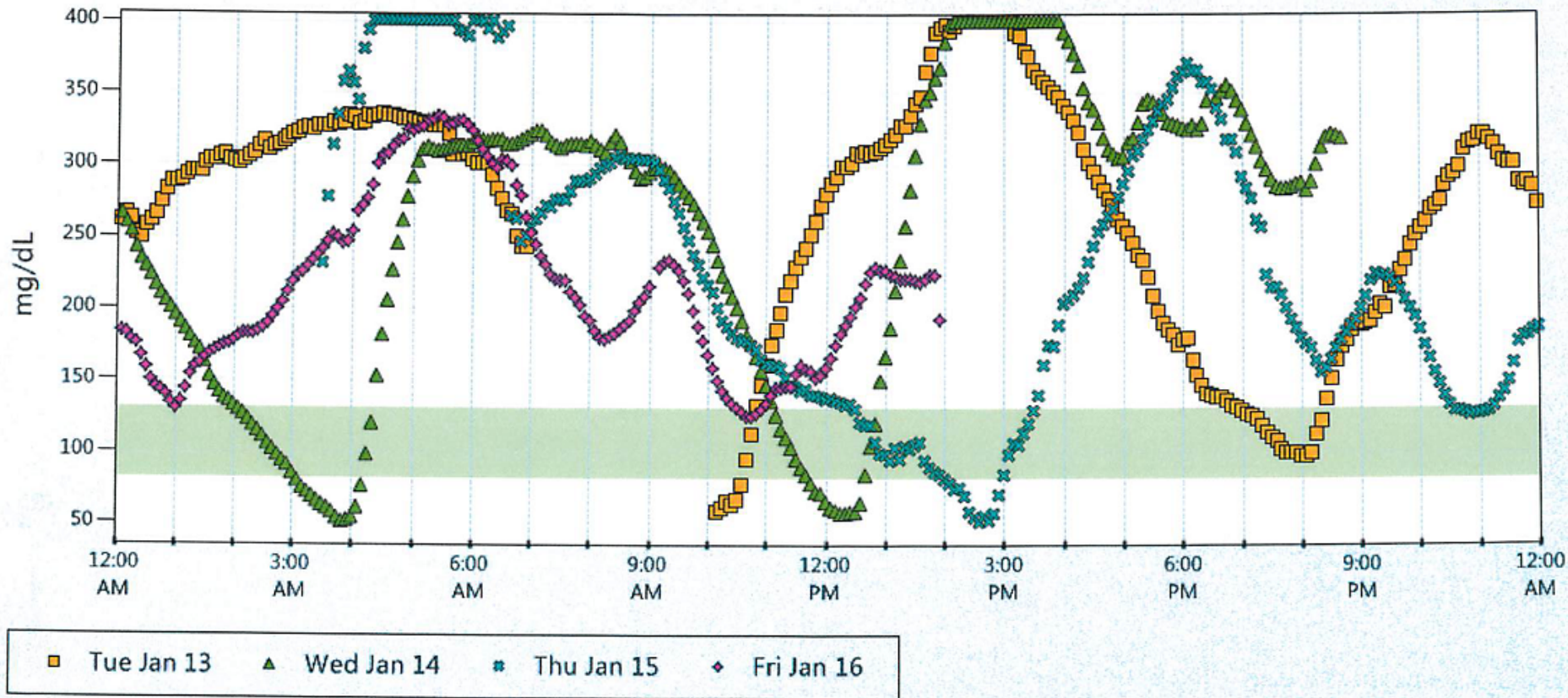
# Type 1 Initial Visit – What's the Problem?

## Type I DM  A1C 9.0%  - Avg BG = 176 (SD=66)

# Type 1 After Pramlintide (Symlin)

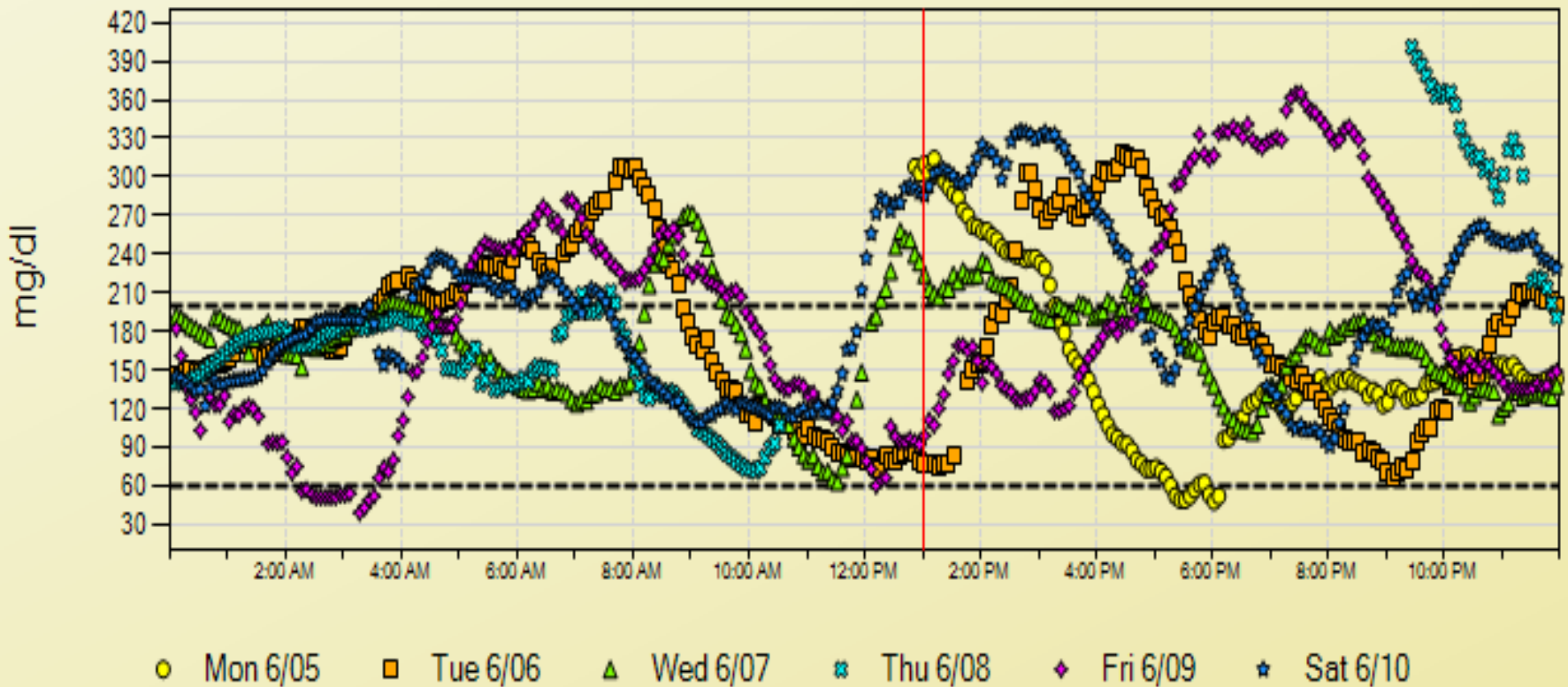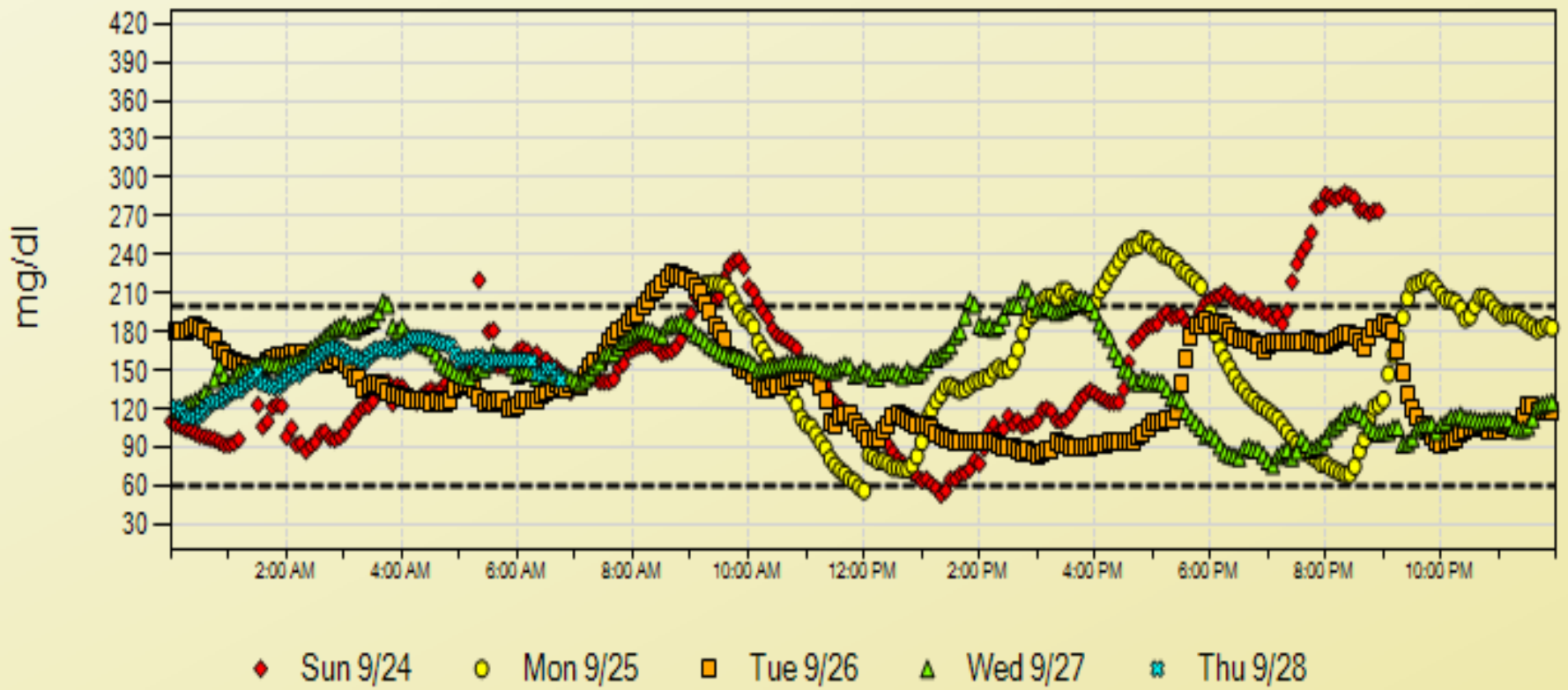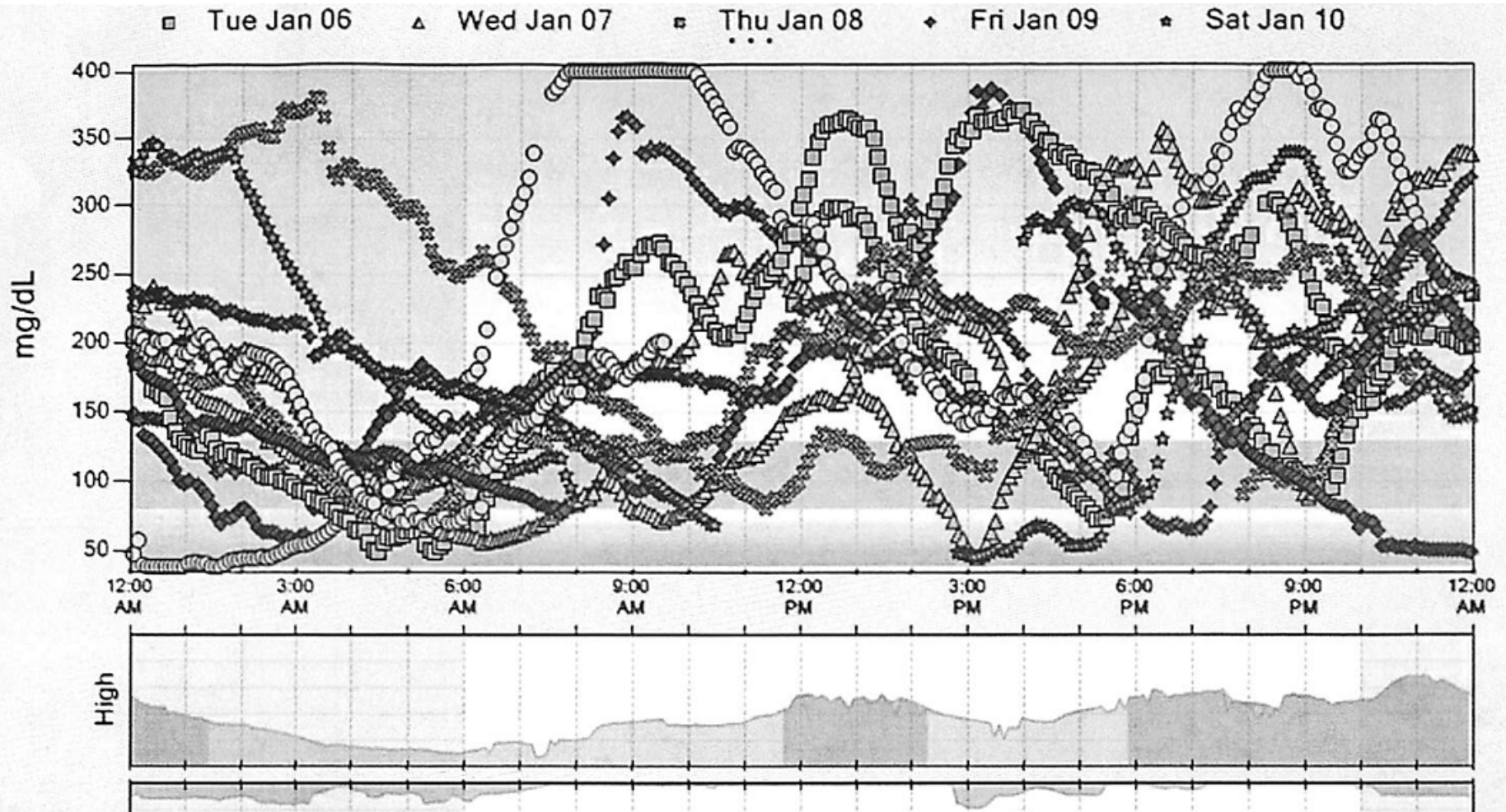## Type I DM  A1C 7.4%  - Avg BG =176 (SD=66)

# Recurrent DKA (A1c 9.5%)

# Recurrent DKA – Reactive Bolusing
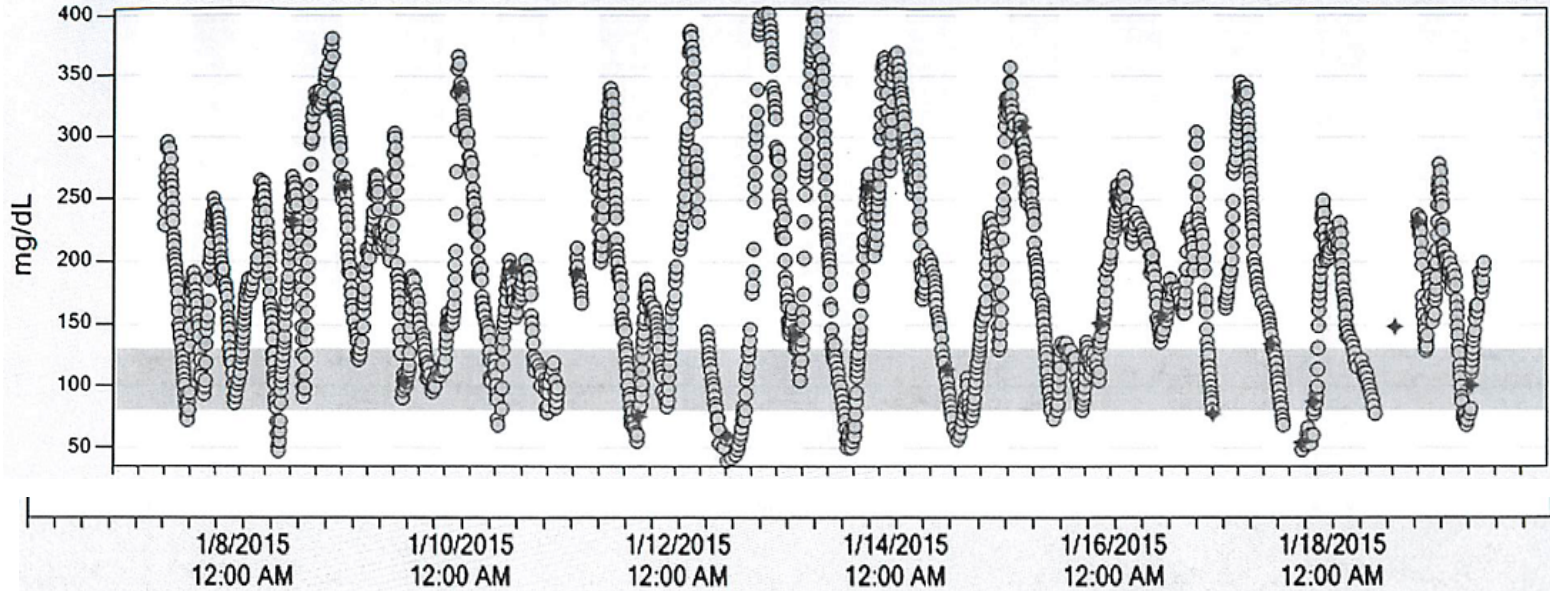


| | 1/6 | 1/7 | 1/8 | 1/9 | 1/10 | 1/11 | 1/12 | 1/13 | 1/14 | 1/15 | 1/16 | 1/17 | 1/18 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total Insulin | | 19.55 | 32.10 | 28.10 | 25.30 | 19.85 | 35.25 | 24.70 | 26.15 | 20.90 | 22.75 | 26.20 | 25.10 |
| Basal (U) | | 35% 6.90 | 44% 14.15 | 50% 14.15 | 56% 14.10 | 65% 12.90 | 32% 11.15 | 42% 10.40 | 50% 13.05 | 67% 13.95 | 61% 13.90 | 53% 13.85 | 56% 13.95 |
| Bolus (U) | | 65% 12.65 | 56% 17.95 | 50% 13.95 | 44% 11.20 | 35% 6.95 | 68% 24.10 | 58% 14.30 | 50% 13.10 | 33% 6.95 | 39% 8.85 | 47% 12.35 | 44% 11.15 |
| # of Boluses | | 5 | 9 | 8 | 6 | 3 | 7 | 4 | 4 | 5 | 7 | 11 | 5 |
| Avg. Bolus (U) | | 2.53 | 1.99 | 1.74 | 1.87 | 2.32 | 3.44 | 3.58 | 3.28 | 1.39 | 1.26 | 1.12 | 2.23 |
| # Corr. Bolus | 100% 5 | 78% 7 | 75% 6 | 83% 5 | 100% 3 | 86% 6 | 100% 4 | 100% 4 | 80% 4 | 100% 7 | 91% 10 | 60% 3 | |

# 72 yo Type 1 with A1c = 6.1%



Post-meal boluses and overcorrections

# Connectivity – the Next Big Wave



- Bluetooth LE allows connecting:
    - Pumps or smart insulin pens
    - Meters and CGMs
    - Cell phones
    - Activity monitors – FitBit, JawBone, MotoActv, BodyMedia
- Integrate data from different device manufacturers
    - Tidepool, DiaSend, Share
- FDA is on board !

# The Near Future

- Connectivity
  - Interoperability
  - Standard Display formats

- CGMs Replace Fingersticks

- Control
  - Assisted
  - Fully-closed loop

# Dexcom BLE Share System



Caregiver's Phone
with Follow App

Wi-Fi or
Cellular

Dexcom Share

Wi-Fi or Cellular

Bluetooth

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# Next Step: Replace Fingersticks
## Sensors vs SMBG

| Performance Parameters | CGM vs. YSI | SMBG vs. YSI |
|---|---|---|
| **TABLE 1: COMPARISON OF CGM, SMBG AND REFERENCE YSI MATCHED** | | |
| Temporally matched pairs (N) | 2263 | 994 |
| Pearson Correlation Coefficient | 0.97 | 0.99 |
| Mean Absolute Relative Difference (ARD) % | 9.0% | 5.6% |
| % 20/20 | 93.0% | 98.8% |
| MARD within Day 1 \| Day 4 \| Day 7 | 10.7% \| 8.0% \| 8.5% | 5.3% \| 4.9% \| 6.6% |
| Mean Absolute Difference (MAD), at Hypoglycemia BG <= 70 mg/dL | 6.4 mg/dL | 4.2 mg/dL |
| MARD at Euglycemia 70 < BG <= 180 | 9.7% | 6.1% |
| MARD at Hyperglycemia BG > 180 mg/dL | 8.0% | 4.8% |
| Overall CEG A+B Zones \| A Zone | 99.5% \| 92.4% | 99.6% \| 98.5% |
| CG-EGA Zone Accurate Readings Hypoglycemia \| Euglycemia \| Hyperglycemia | 95.6% \| 99.1% \| 99.2% | 97.3% \| 99.7% \| 99.6% |

89% of the CGM readings are ± 20% of YSI (or ±20 mg/dL for YSI ≤ 100 mg/dL)

Chang A, Nalamura K, Bailey TS, Christiansen M, Bhavaraju N, Price D. RT-CGM Performance Ready for Independent Diabetes Management Decisions. ADA 2014; abstract 840P.

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# Factory Calibration

- First step to fingerstick replacement

- Available today in E.U. without a prescription
  - Abbott  Freestyle Libre (MARD 11.5%)

# Troubleshooting the Infusion Set

# Infusion Set Failure Is Common

- Most of the 16,849 adverse pump events reported to the FDA between 2006-2009[1] involved infusion sets[1]

- A 2006 review of pumps in France likewise found that most serious adverse events involved infusion sets[2]

- Auto-insertion devices have a high failure rate of 8.9%[3]

1 www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralHospitalandPersonalUseDevicesPanel/UCM202779.pdf

[2] Maugendre D. Technical risks with subcutaneous insulin infusion. Diabetes Metab. 2006;32:279-284.

[3] Renard E, et al: Lower rate of initial failures and reduced occurrence of adverse events with a new catheter model for continuous SQ insulin infusion. Diabetes Technol Ther 12:769-773, 2010.

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# Infusion Sets –
## The Achilles Heel Of Pumps

Survey of 1142 pumpers in 40 German diabetes clinics

- 54% reported an increase in glycemia for unknown reasons until their infusion set is changed

- 19% reported kinking, 12% had leakage, 12% air bubbles, and 33% had other issues

- 36% used auto-insertion devices – 72% of them reported that the device failed to work ~10% of the time

Reichert D, et al. Realität der Insulinpumpentherapie in Diabetesschwerpunktpraxen: Daten von 1142. Patienten aus 40 diabetologischen Schwerpunktpraxen. Diabetes, Stoffw. und Herz 22: 367-375, 2013.

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# Infusion Sets
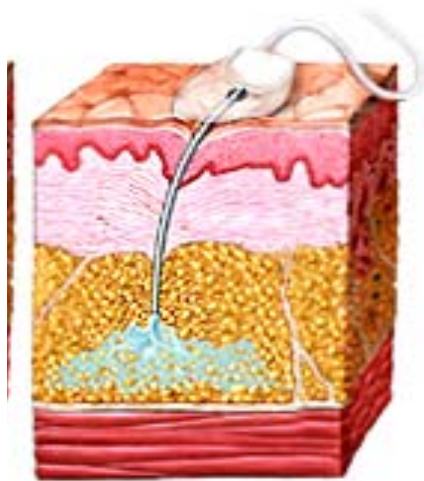


External insulin pump



- Subcutaneous indwelling catheters

- Teflon cannula or steel needle

- Change Teflon every 3 days (3.4 d*) and steel every 2 days (3.7 d*)

- Pump and tubing may be disconnected without removing insertion site
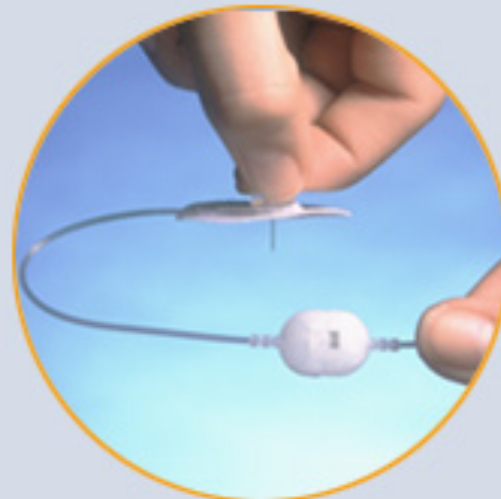
  * >500 self-reports of length of use in U.S.

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# Cannula Options
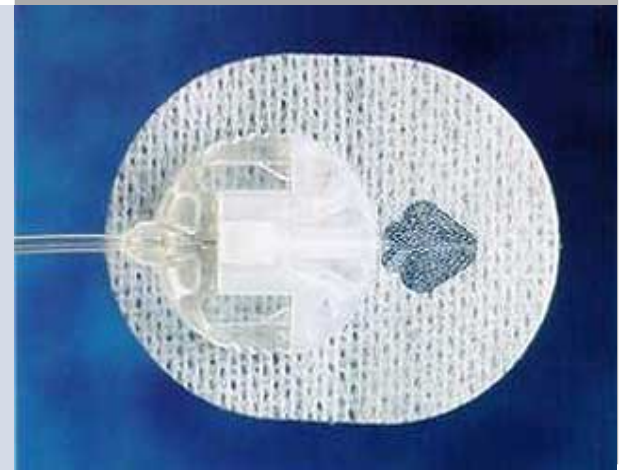
Straight

Slanted

Teflon

Metal

Teflon

6, 9 mm

4, 5, 6, 9 mm
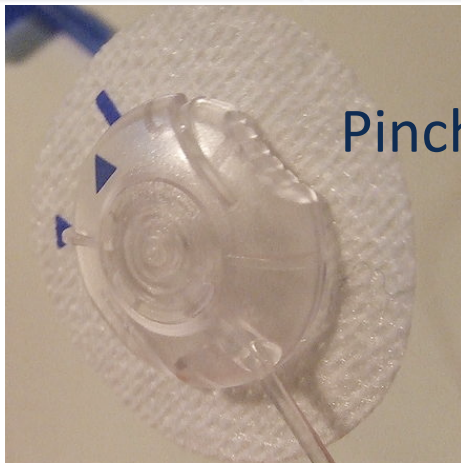
13, 17 mm

# Line Disconnect Mechanisms

Motion and degree of manual dexterity required



Twist & pull
easiest



Pinch & pull
easier

Pinch, twist, & lift
hardest

Pinch & lift
harder

Tubing lengths: 24", 32", and 43" for most sets

# Auto-Inserters

Inset 30

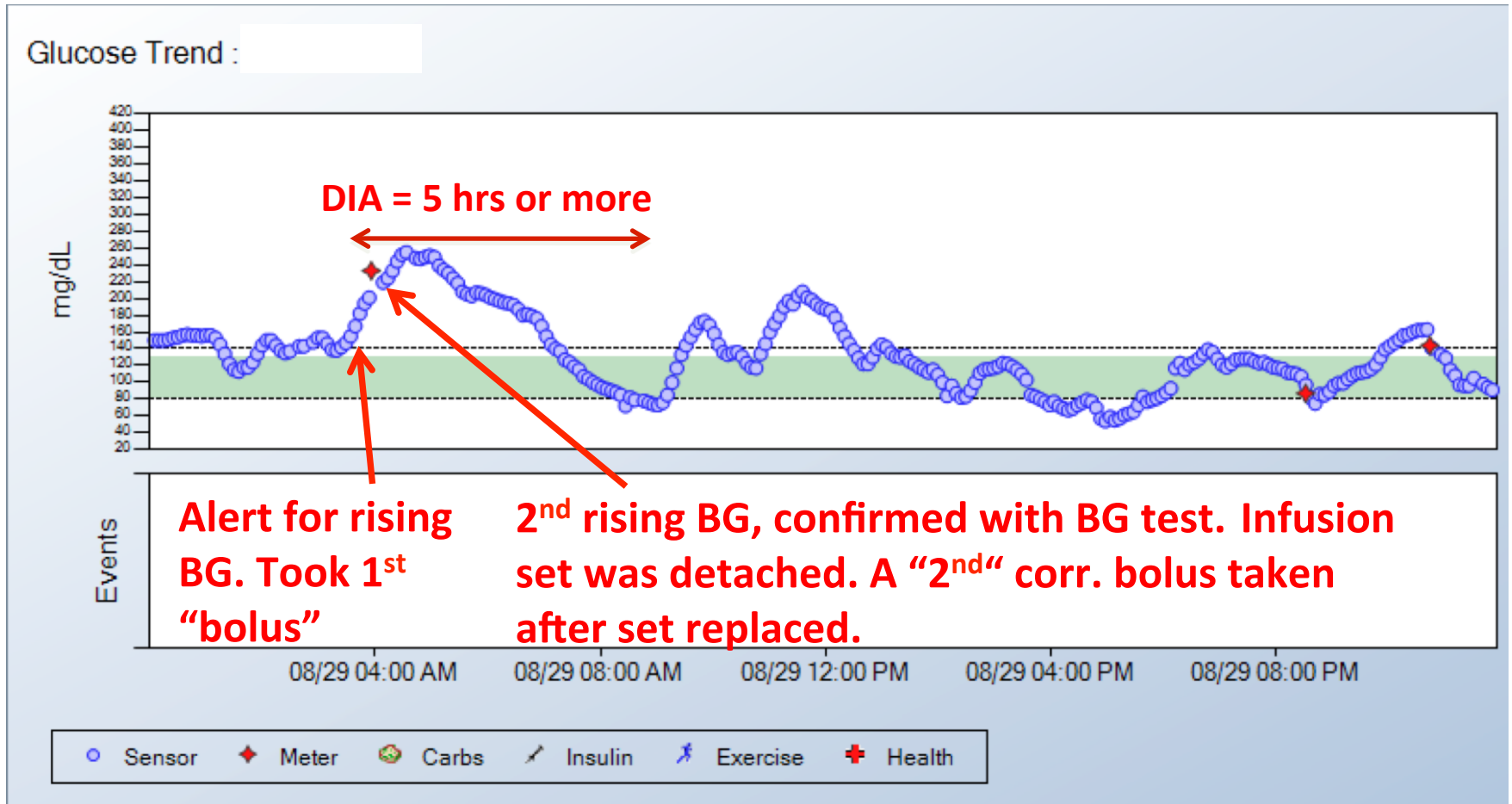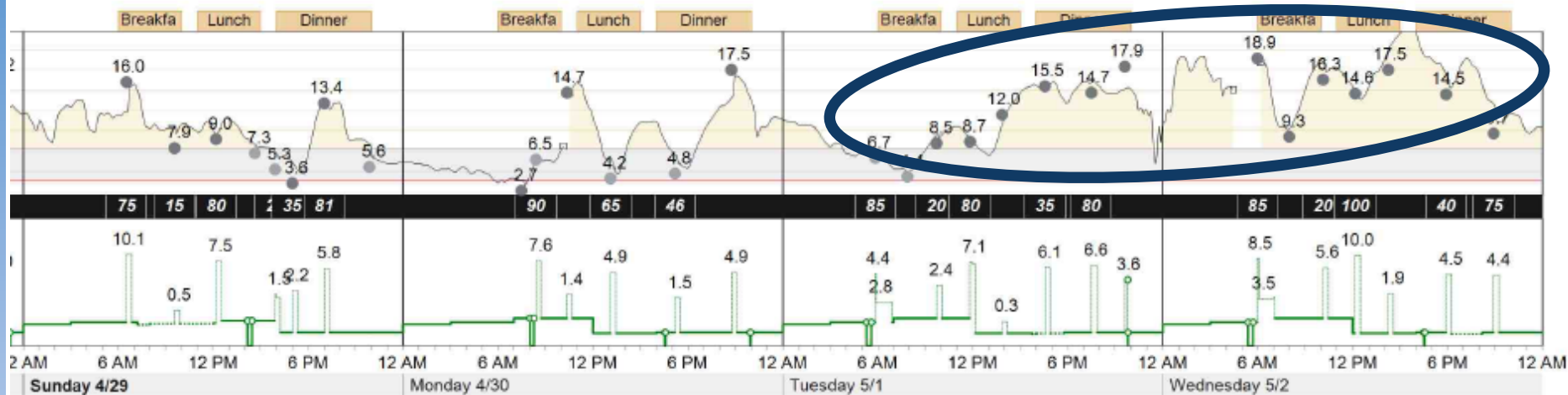Accu-Chek Link Assist

Inset/Mio

Quick-Serter

Cleo

Omnipod

# Is The Infusion Set The Problem?

- Sites often "go bad"?

- Have "scarring" or "poor absorption"?

- Often have 2 or more unexplained highs in a row?

- Do correction boluses sometimes not work?

- High BGs until the set is changed?
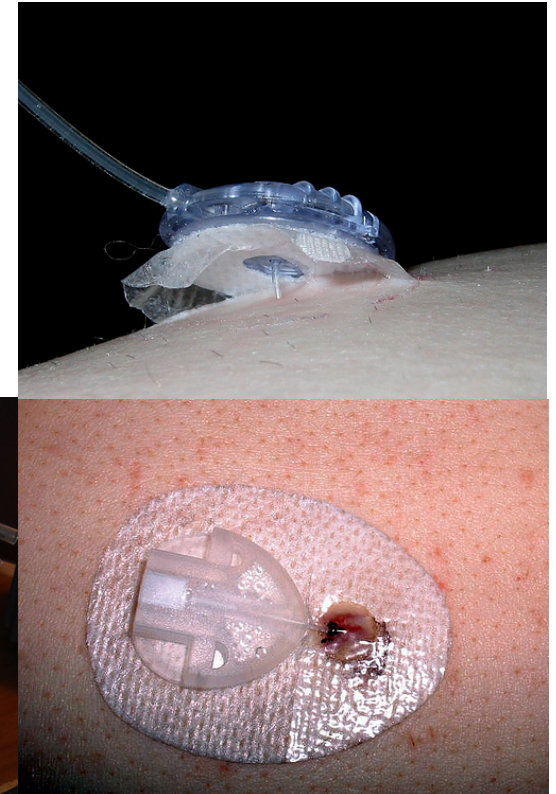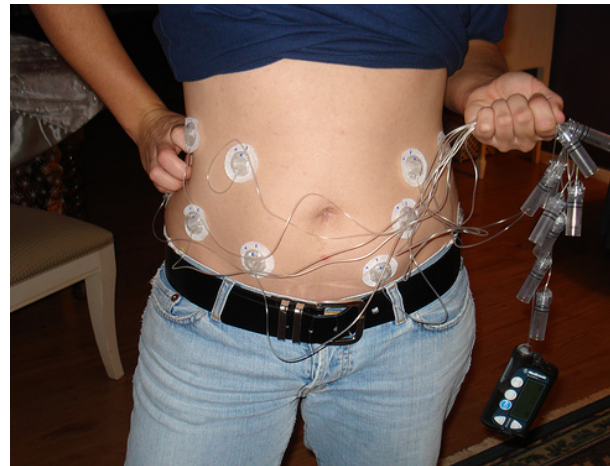
# Infusion Set Failure On CGM

# Infusion Set Failure



Set problem started on afternoon of May 1$^{st}$ and lasted until late in the day on the 2$^{nd}$ when the infusion set was changed.

# How Infusion Sets Fail

- Complete pullout

- Insulin leak along Teflon to skin

- Hematoma under the skin

- Autoinserter

- Occlusion

- Loose hub

- Punctured line

Goal: Less than one failure a year!

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# Stop Infusion Set Problems!!!

- Anchor the infusion line with 1" tape*

  - Stops tugs and pullouts, "unexplained highs" (insulin leaks), skin irritation and "pump bumps"

- Insert set by hand

- Review site prep and insertion technique with clinician or trainer

- Switch to a reliable infusion set

**No anchor!**

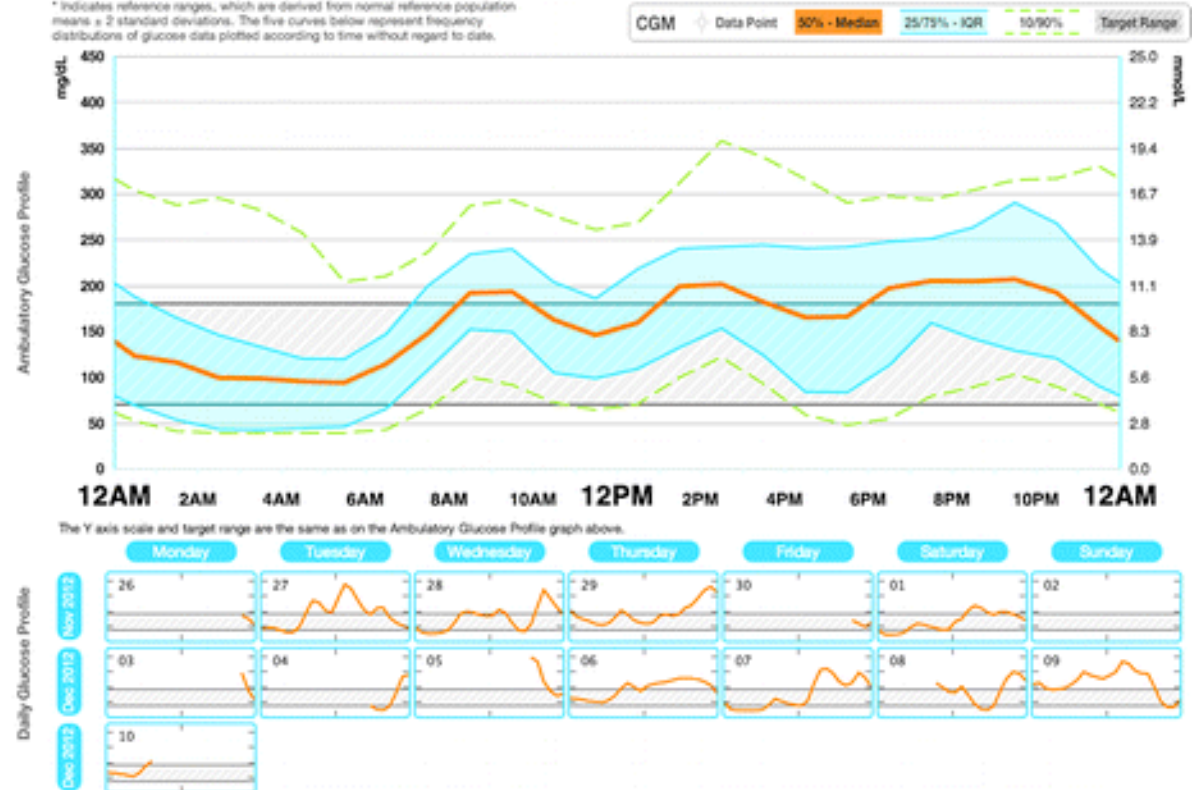\* Transpore, Durapore, Hypafix, Micropore

# Data Tools and Standardized Data

# Use Data Tools

- "On-board" information

- Pump Download software
  - Use with sensor and bG downloads

- Decision Support software

# Ambulatory Glucose Profile for CGM Data

Interna. Diab. Center

- Time in range

- Shaded modal day
  with median,
  IQ range, and
  10/90% range

- Dashboard

Bergenstal et al: DT&T 2013

# Freestyle Libre/Flash Glucose Patterns
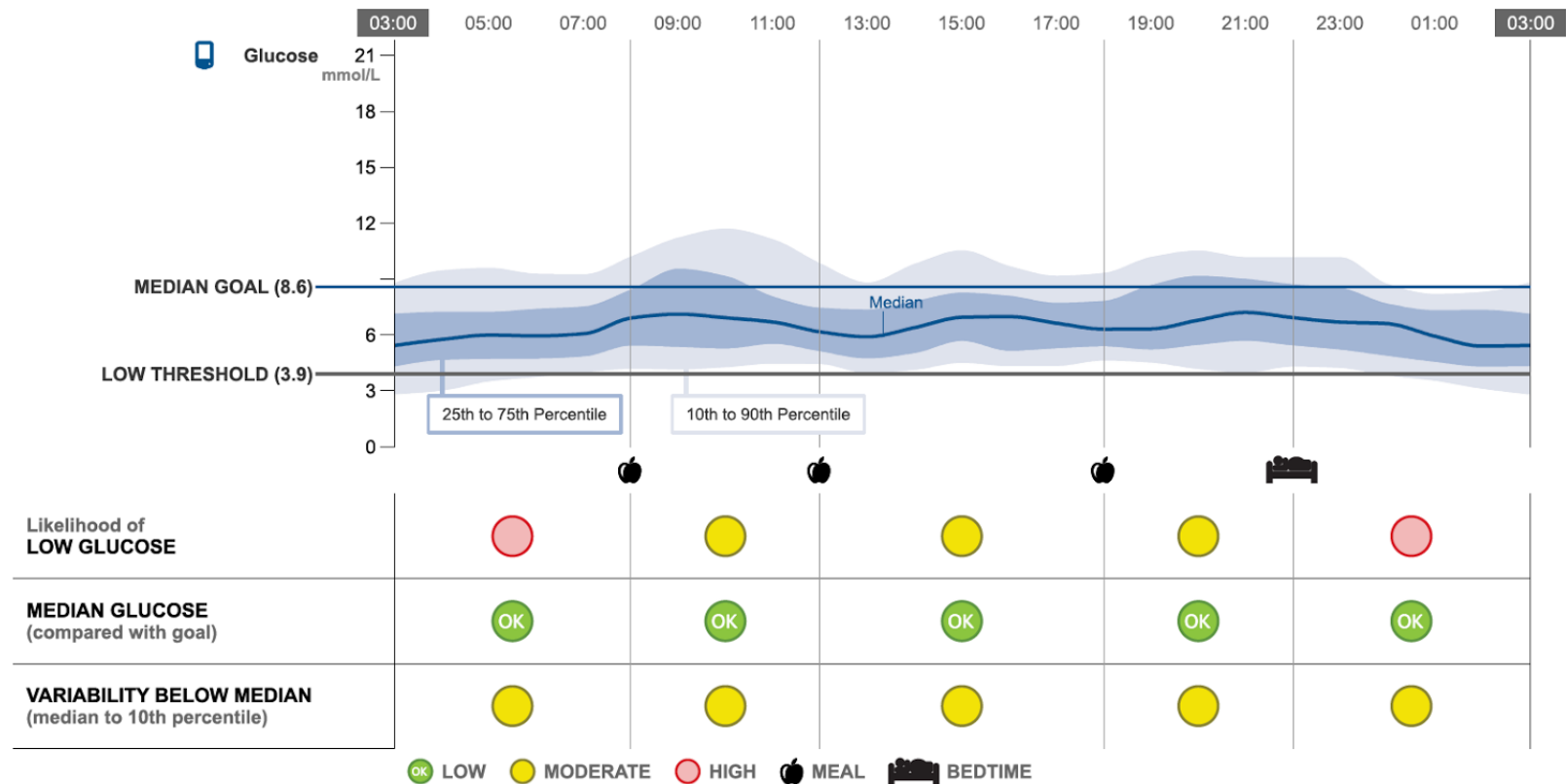
# Diabetes Management System



- Automated report
- Facilitates patient counseling
- Discloses educational deficits
- Recommends device settings
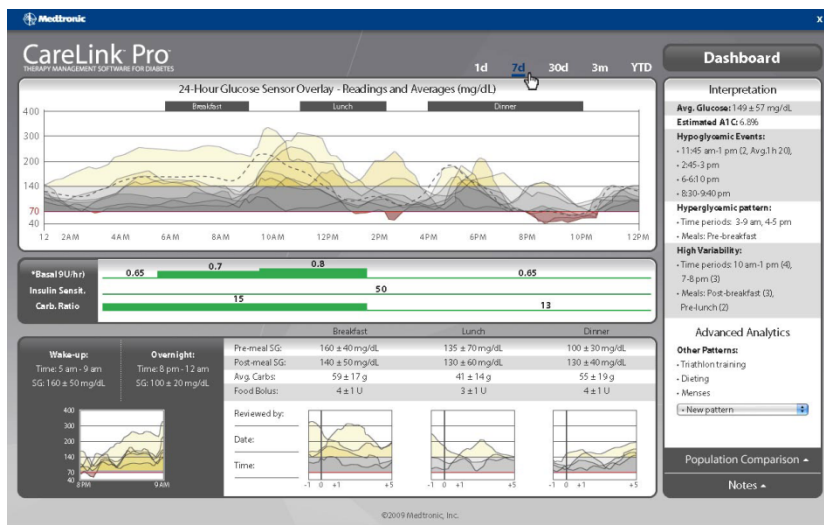
- Tracks glycemic outcomes
- Understands behaviors
- Informs health care provider

# Review Data On The Device
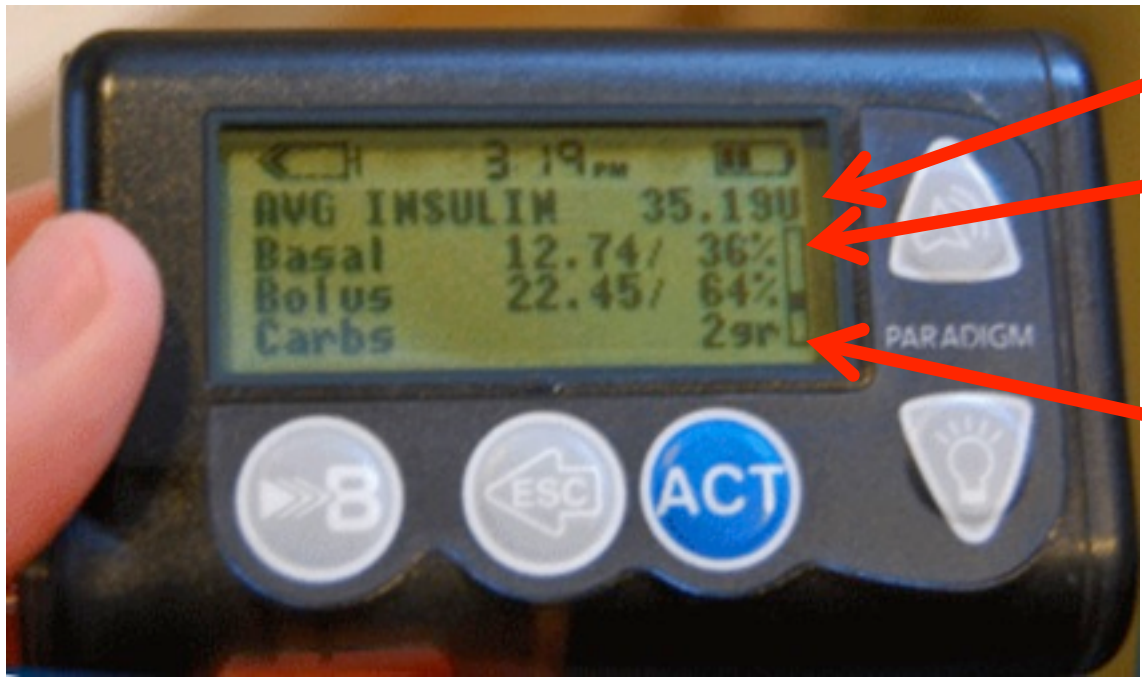


**TDD** = 35.19 u

**Basal %** is low at 36%

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

# Connectivity

Get ready –the next big wave in diabetes devices and care!

Gadgets
+ Interfaces
+ Intelligence

Eventually, easier for everyone

# Going Beyond Simple Pumps

- Show how a setting change affects the TDD (& BG)

- Temp basal PLUS bolus doses

- Super Bolus

- Meal-size boluses

- Alert for excess BOB (bolus without BG but BOB is ++)

- Low BG predictor (HypoManager)

- Exercise compensator (duration + intensity = gr of carb)

- Automated basal and bolus testing

# Faster Insulins

- Diaport intraperitoneal delivery

- Faster insulin analogs

    - Novo Nordisk

    - Lilly

    - Biodel

    - MannKind Afrezza (inhaled)

- Micro-needles (1.5 mm)

- Oral insulin

Goal: fewer highs and fewer lows

# Implanted CGMs



Dexcom G1 2004



Sensionics

- Months to years of use
- No disposables
- Minor surgery
- Revenue model ?



Biorasis Glucowizzard

Implantable glucose sensor 0.5 x 0.5 x 5 mm

Regular 18-gauge hypodermal needle utilized for sensor implantation

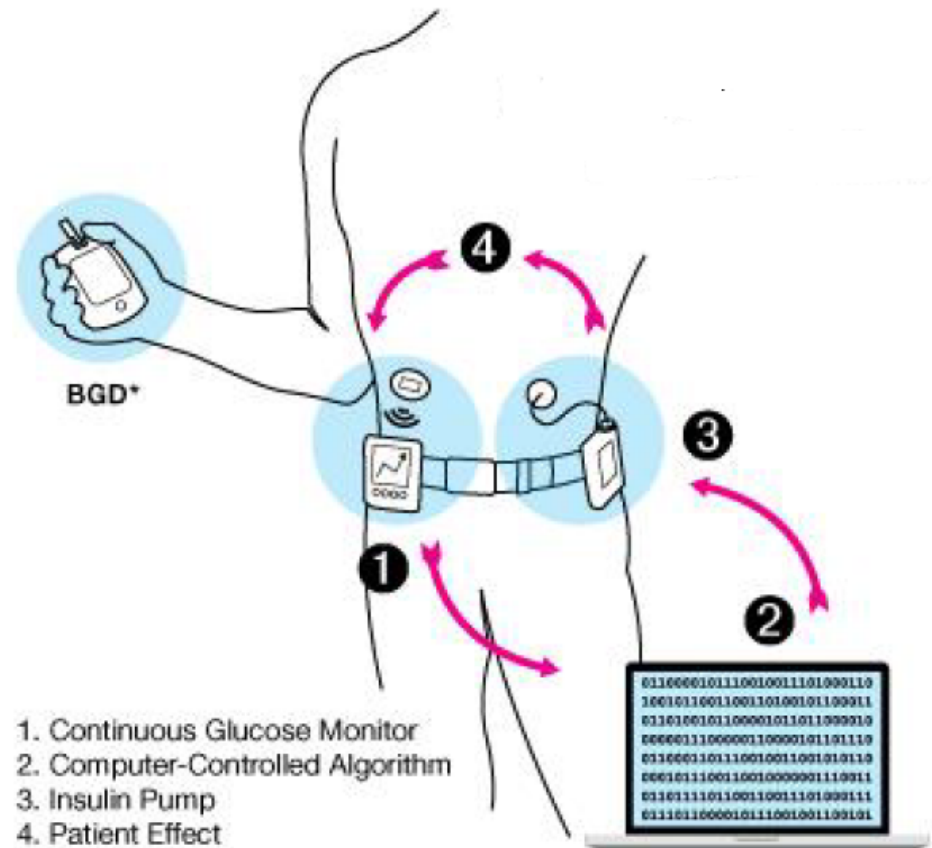Continuous monitoring and recording of glucose levels
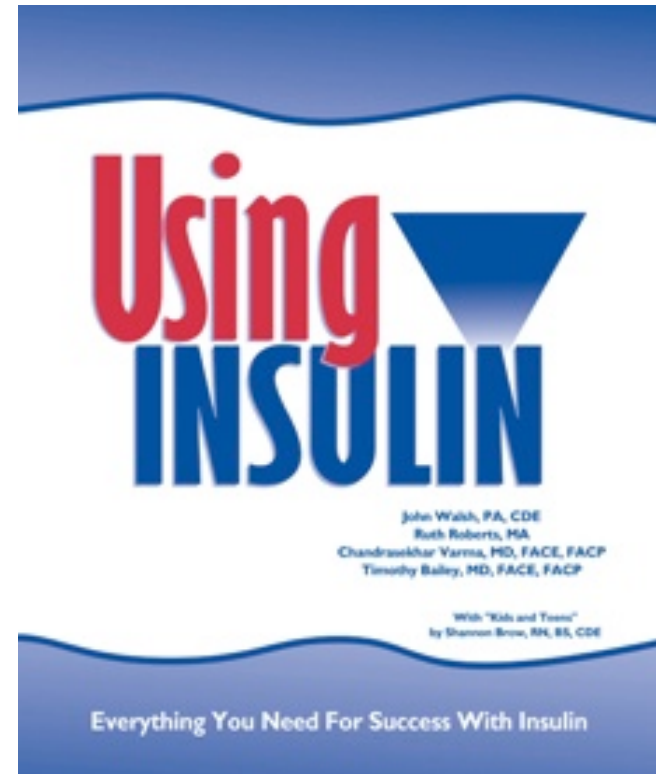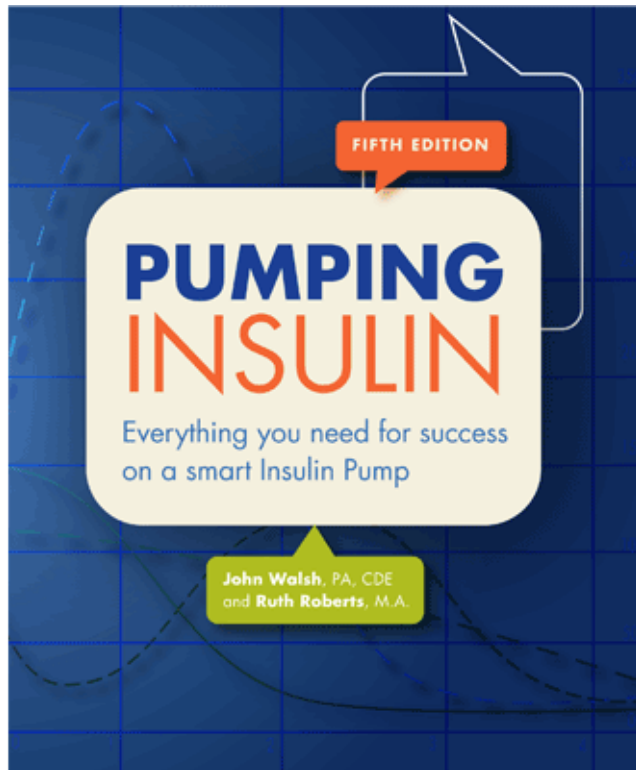


GlySens

JDRF
typeonenation

# Artificial Pancreas Pathway

- Threshold Suspend
  - Reactive
  - Predictive

- Control to Range

- Control to Target
  - Insulin-only
  - Bi-hormonal



BGD+

1. Continuous Glucose Monitor
2. Computer-Controlled Algorithm
3. Insulin Pump
4. Patient Effect

fda.gov GuidanceDocuments/UCM259305.pdf

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