



Clinical Need & Technology (Insulin Delivery)

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Insulin pens, insulin pumps Clinical Need

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Certified Diabetes Technology Clinician Course
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Insulin Pens

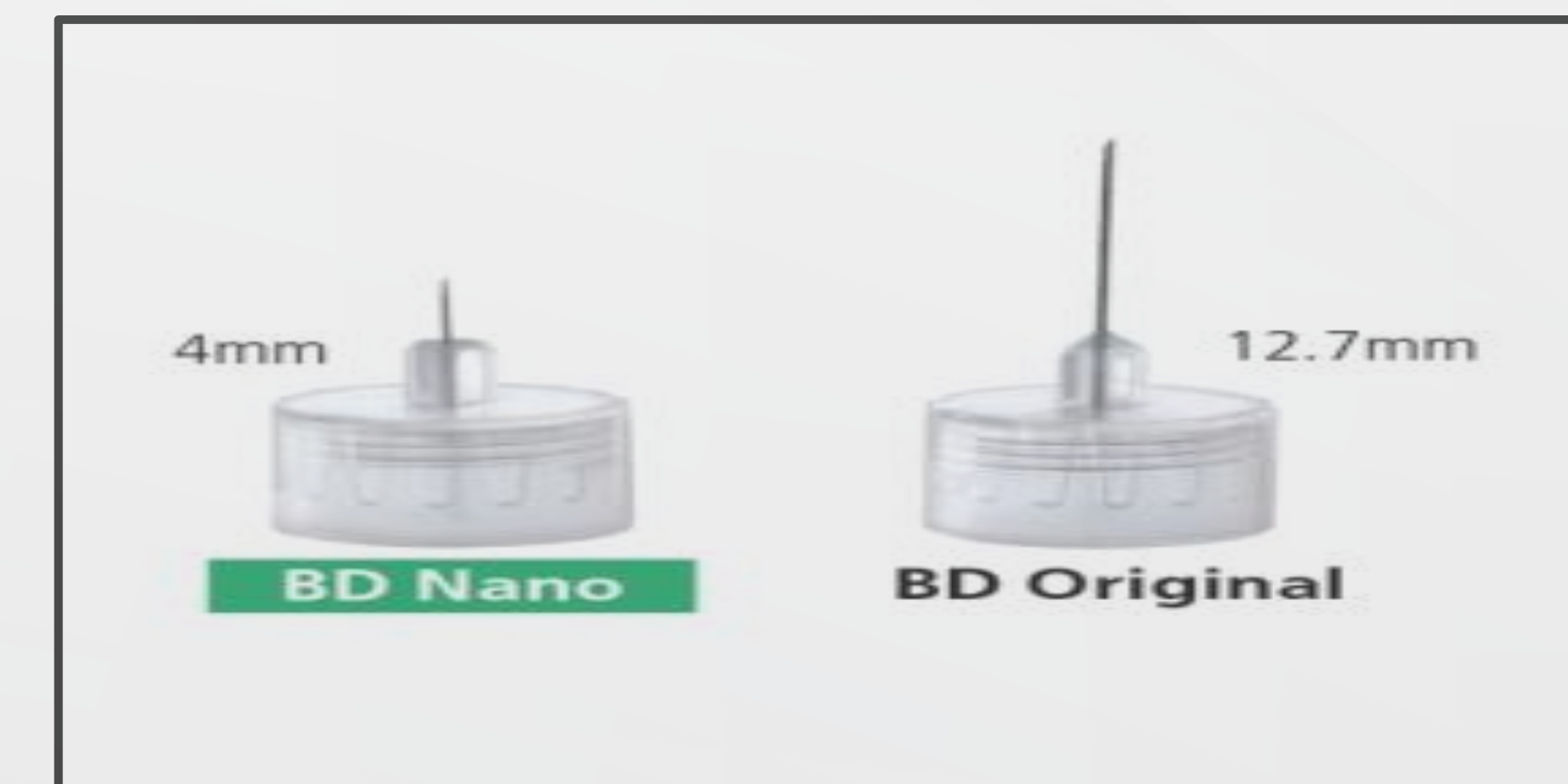


Pens, pens and more pens



Advantages of Insulin Pens

1. More accurate dosing
2. Greater convenience
3. Smaller needle lengths, 4 mm, instead of 6 mm
4. Makes it possible for visually impaired to self administer insulin safely
5. HumaPen Luxura and Echo are re-useable pens with cartridges and capable of delivering 0.5 units for kids and insulin sensitive adults

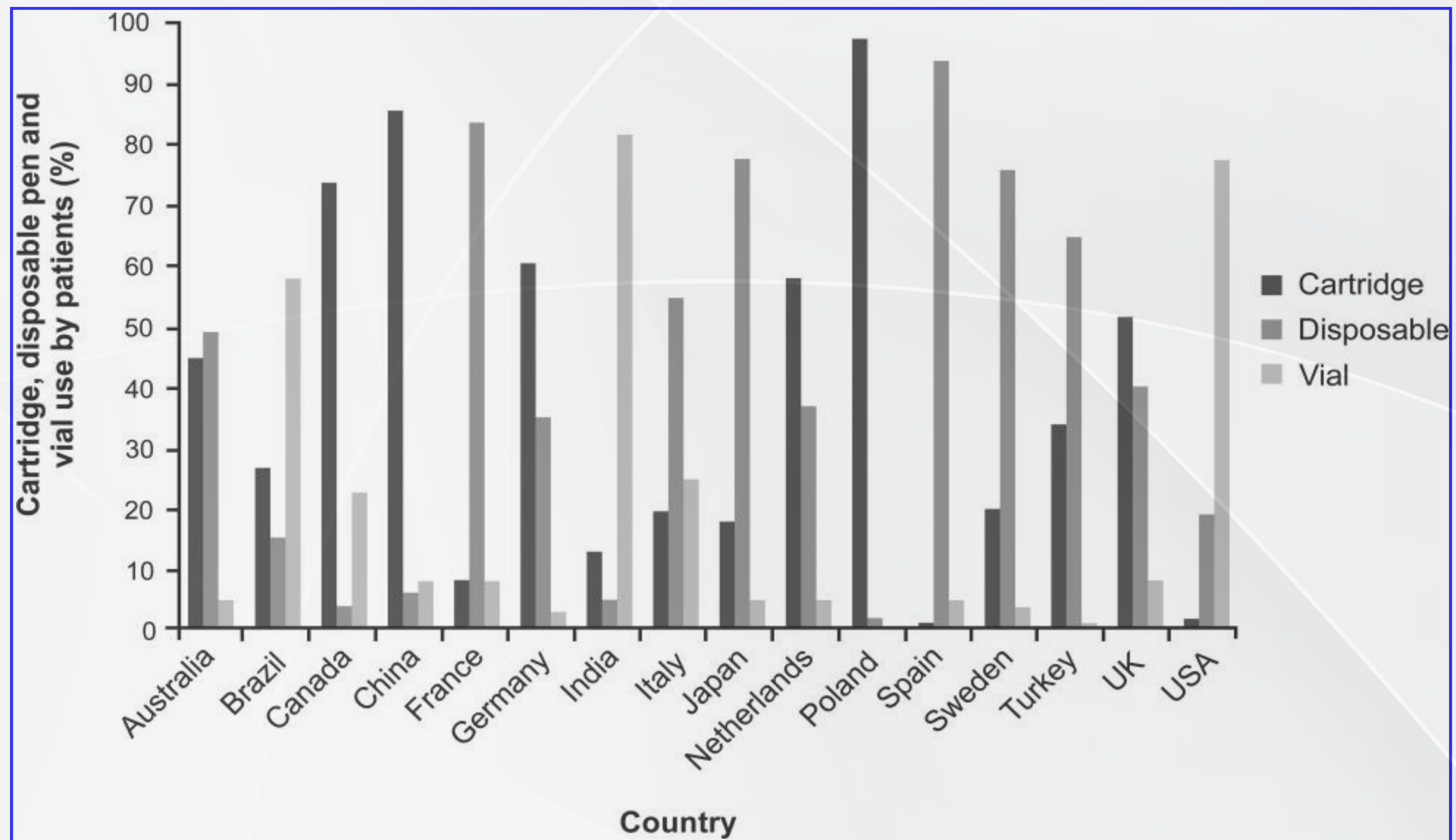


Echo Pen (not just for kids...)

This pen has a memory, even when your patient doesn't.



Worldwide Pen Use: 2009



Diabetes Tech Therap 12 (Suppl 1)S79-S85, 2010



Insulin Concentrations: units/ml

U 100:

Apidra
Humalog
Novolog

Regular

Humalog 75/25
Humalog 50/50
Humulin/Novolin 70/30

NPH

Lantus
Levemir
Treciba

U 200:

Humalog
Treciba

U500:

Humulin Regular

U300:

Toujeo



All insulin pens are not created equal

Ways in which pens differ from one another:

- Type(s) of insulin available
- Disposable vs. refillable cartridge
- Unit increments delivered in single dose (0.5, 1, 2 or 5 units)
- Largest dose available (30 to 300 units)
- Strength & dexterity needed to operate pen
- The size/color of the numbers on the dosing dial
- Loudness of dosing clicks



Steps in Insulin Pen Teaching

1. **New needle** every time
2. **2 unit prime** dose with all pens, every injection
3. Hold the needle in place for a **count of 10**
4. **Remove needle** after the injection

Pens can be un-refrigerated for 28 days typically; 14 days for mixed insulin; 42 days for Levimir

Each u 100 insulin pen holds **300 units**

Insulin Pumps

We've come a long way, baby



Brands of Insulin Pumps

Animas Ping/Vibe



Insulet Omni Pod



Medtronic Revel/530G



Tandem t:slim, t:slim G4, t:flex



Valeritas V-Go

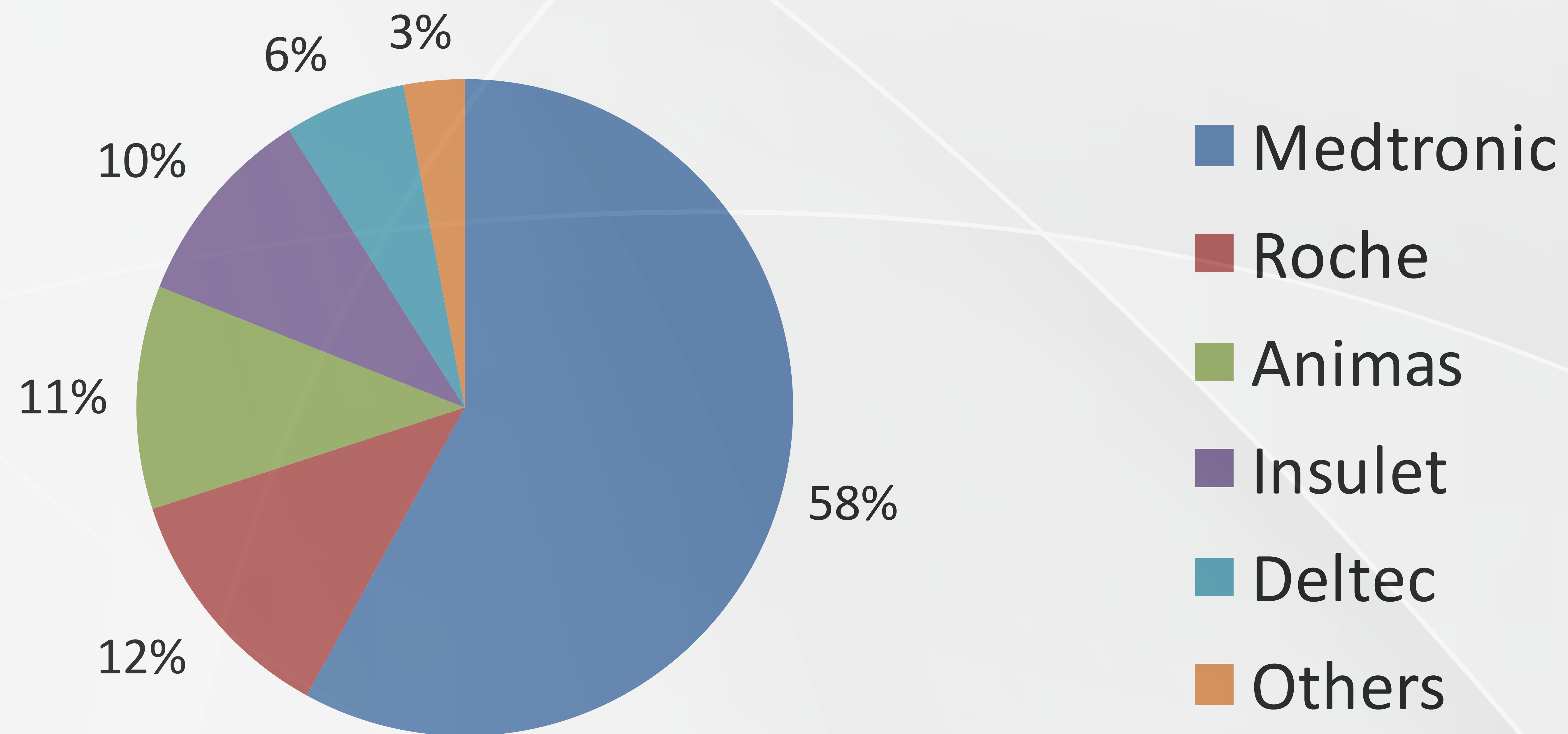


Roche Accu-Chek Spirit Combo



Global Share of Insulin Pump Market

Based on Revenue



Source: D. Medical Industries LTD. - 2012 SEC Form 6-K
<http://www.sec.gov/Archives/edgar/data/1487525/000117891312003364/zk1212349.htm>

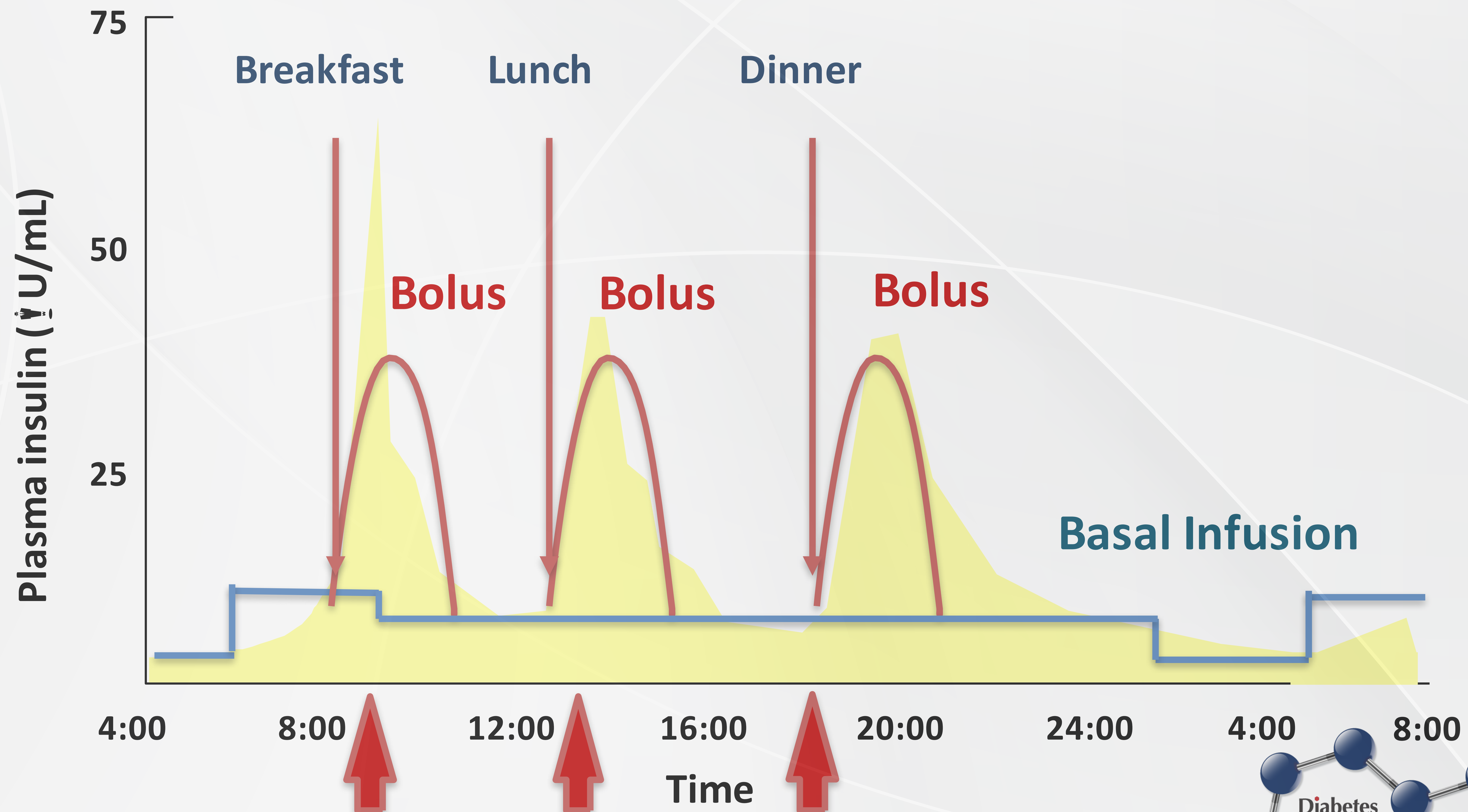


Clinical Indications for Pump Therapy

- Hypoglycemia, main reason prescribed
- Flexibility, main reason patients desire a pump
- Dawn phenomenon
- Pregnancy
- Children, especially infants and toddlers
- Erratic lifestyle, especially shift work
- Exercise, especially for elite athletes
- Ability to give “designer boluses”



Variable Basal Rates



CSII=continuous subcutaneous insulin infusion.



Pump Disadvantages

- Takes longer to learn than MDI
- Requires more attention to detail and more frequent blood glucose monitoring
- Carb Counting vital to success
- More expensive, so insurance is a MUST
- Sites can easily become overused
- **Potential increased risk of DKA**



What makes a successful pumper?

- Takes responsibility for communication w HCP
- Tests BG frequently (≥ 6 times/day)
- Willing to learn and practice self management
- Has health insurance
- Capable of good problem solving
- Understands the risk of DKA
- Carries the back up supplies needed to prevent DKA and treat hypoglycemia

Scheiner, G. (2012). Think like a pancreas.



Supplies To Carry At All Times

- Insulin
- Way to administer insulin (syringe/pen needles)
- Glucose meter
- Glucose tabs
- Medical Alert
- Batteries
- Way to check for ketones (not easy)



Pump Training & Initiation

- Which pump, which CGM, which insulin?
- Initial doses: weight based vs. % of TDD
- Saline trial vs. Insulin @ start?
- CGM before vs. after pump initiation?
- Health care team training vs. pump Co. CDE?
 - Who does the adjustments? For how long?
- Single basal rate vs. multiple rates?
- Support persons trained/school personnel



Issues in Pump Initiation: weight based vs. % of TDD

- Most patients starting pumps do not have an optimal A1c, so there is inaccuracy in using current doses
- Use only 40% basal for anyone who is pregnant or with a history of severe hypoglycemia
- Typically, start with a single basal rate
- Use CGM data, if available to determine times of basal changes



Issues in Pump Initiation: saline vs. no saline start

- Regional differences
- Advantages of saline starts: gives pts. an opportunity for practice with 'no harm'
- Disadvantage is that patients cannot see the effects of pump use while still injecting insulin
- Prolongs the training time
- Pump companies discourage saline starts



OUTCOMES: SA Pumps vs. MDI

- 2012, Slover, et al
 - Comparison: sensor-augmented pump (SAP) vs. MDI
 - 82 children + 74 teens
 - ↓ in A1c, lower AUC values for hypo in SAP group
 - ↓ hyperglycemic excursions in SAP group
 - ↓ glycemic variability in SAP group

Slover R, Welch J, Creigo A et al (2012). *Pediatr Diabetes* 13: 6-11.



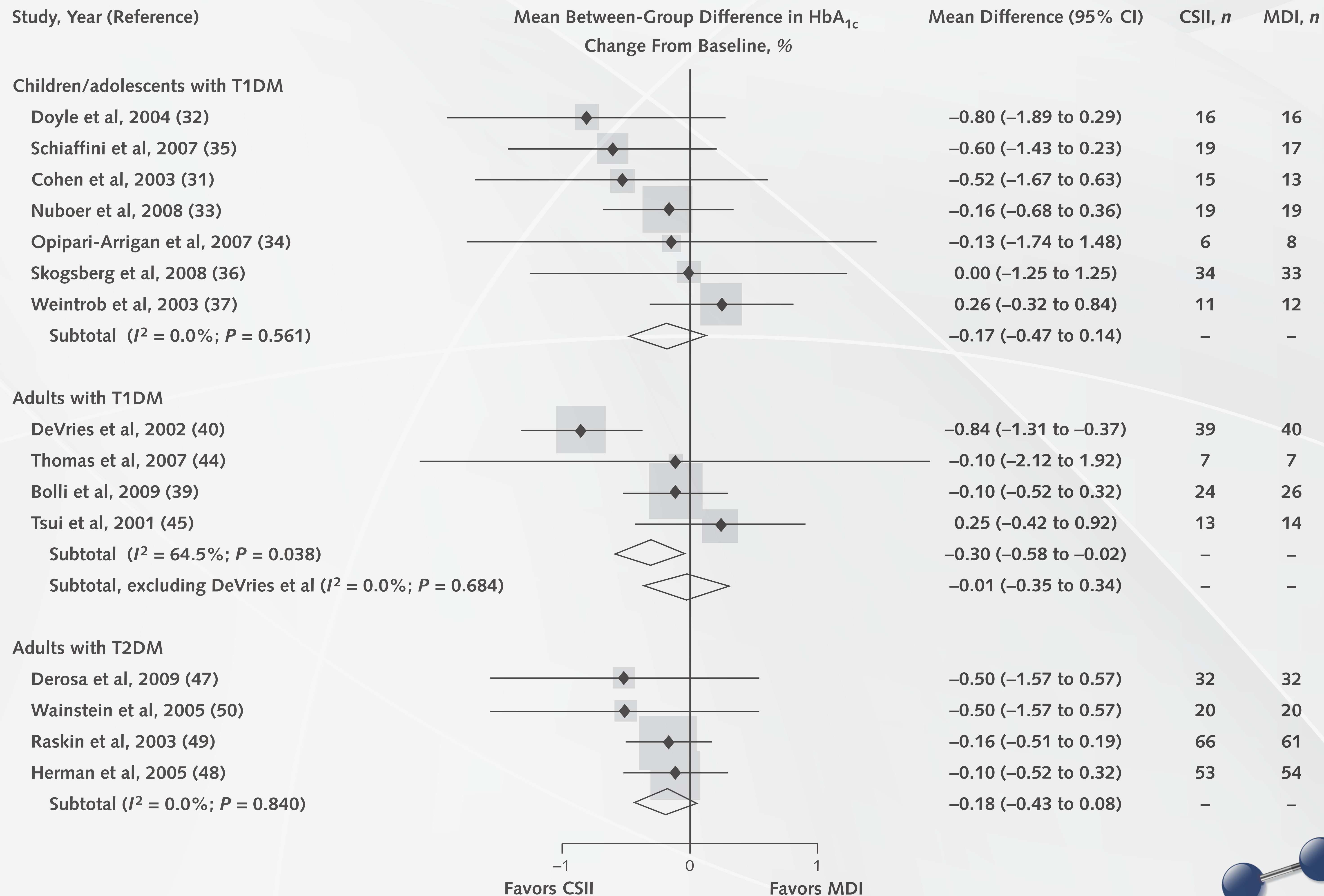
Outcomes: SA Pumps vs. MDI

- 2012, Bergenstal et al
 - 6 mo. single crossover con't of STAR 3
 - 420 subjects who completed 1 yr. RCT
 - 7.4% A1c in SAP group initially
 - 8.0% A1c in MDI group initially
 - ↓ to 7.6% in crossover group
 - ↓ in A1c sustained in children and adults

Bergenthal RM et al (2011). *Diabetes Care* 34: 2403-2405.



AHRQ Review Insulin Pumps--CSII vs. MDI



AHRQ Review Insulin Pumps: SAP vs. MDI + SMBG

Study, Year (Reference)

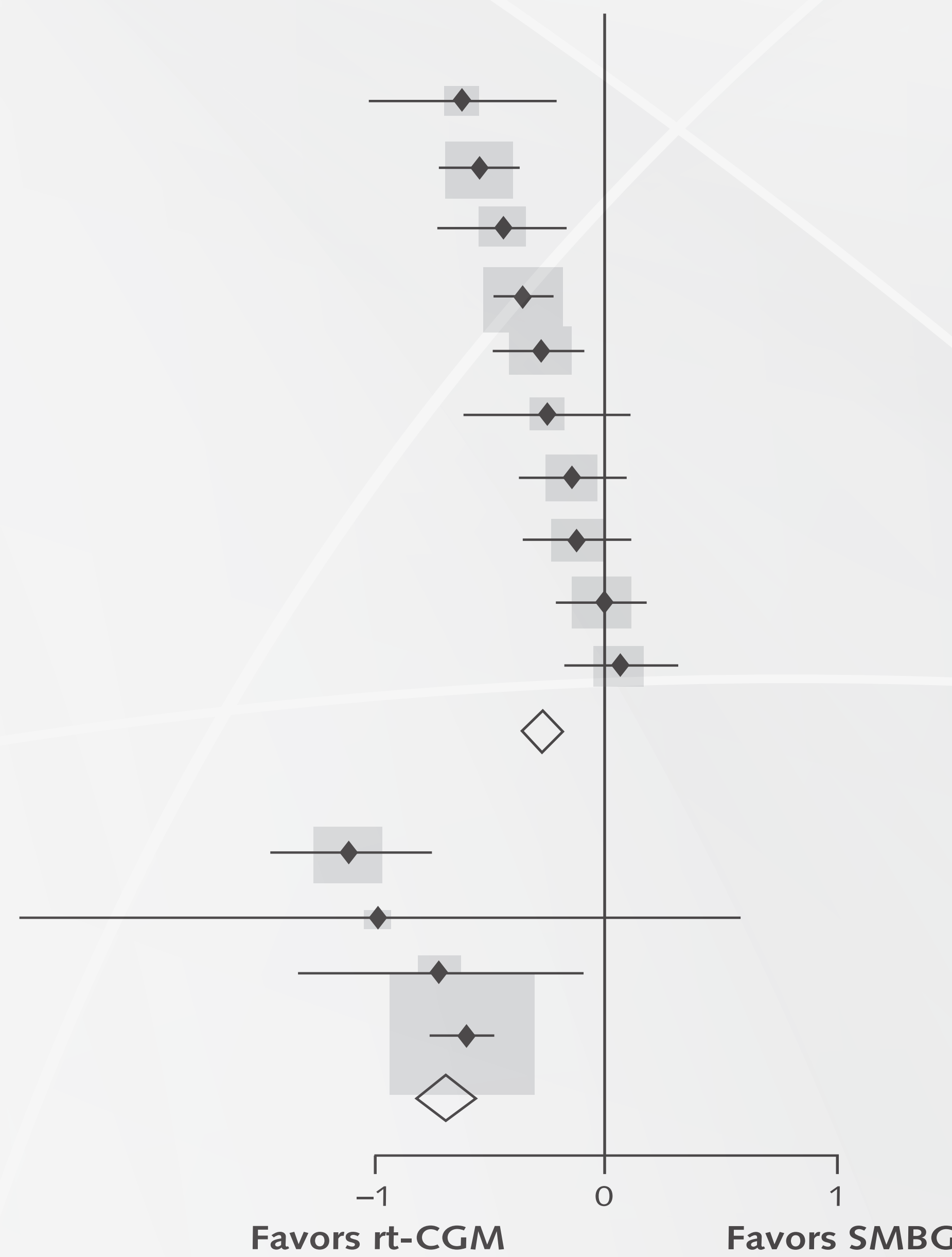
rt-CGM vs. SMBG

- Deiss et al, 2006 (58)
- Tamborlane et al, 2008 (56)*
- O'Connell et al, 2009 (55)
- Beck et al, 2009 (54)
- Battelino et al, 2011 (59)
- Racah et al, 2009 (53)
- Tamborlane et al, 2008 (56)†
- Hirsch et al, 2008 (57)
- Mauras et al, 2012 (60)
- Tamborlane et al, 2008 (56)‡
- Subtotal ($I^2 = 69.9\%$; $P = 0.000$)

SAP vs. MDI plus SMBG

- Hermanides et al, 2011 (66)
- Lee et al, 2007 (65)
- Peyrot and Rubin, 2009 (64)
- Bergenstal et al, 2010 (63)
- Subtotal ($I^2 = 53.7\%$; $P = 0.091$)

Mean Between-Group Difference in HbA_{1c} Change From Baseline, %



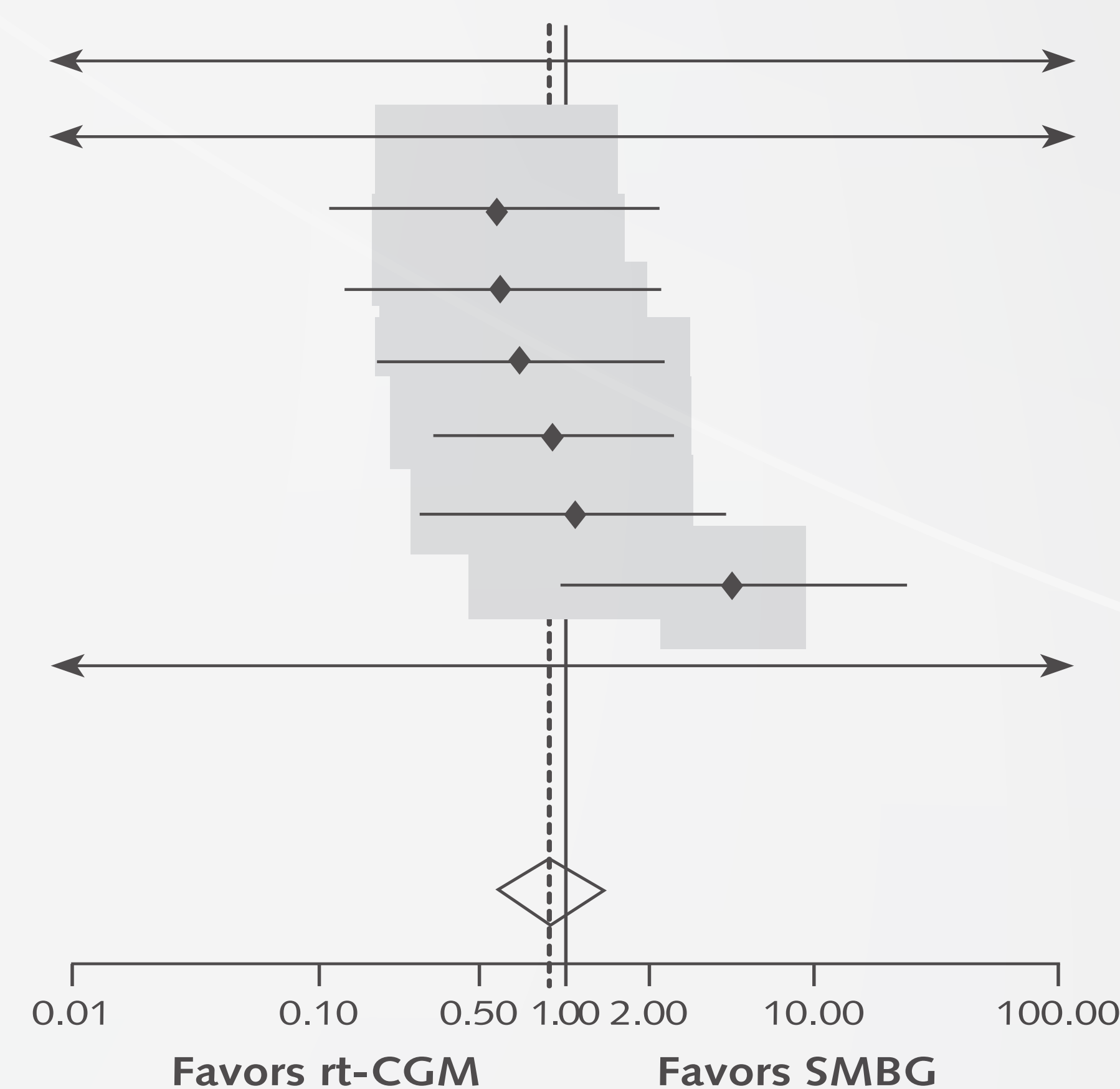
Mean Difference (95% CI) rt-CGM, n SMBG, n

-0.60 (-1.01 to -0.19)	27	27
-0.53 (-0.71 to -0.35)	52	46
-0.43 (-0.71 to -0.15)	26	29
-0.34 (-0.48 to -0.20)	67	62
-0.27 (-0.47 to -0.07)	62	54
-0.24 (-0.61 to 0.13)	55	60
-0.13 (-0.37 to 0.11)	56	58
-0.11 (-0.36 to 0.13)	66	72
0.00 (-0.20 to 0.20)	69	68
0.08 (-0.17 to 0.33)	57	53
-0.26 (-0.33 to -0.19)	-	-
-1.10 (-1.46 to -0.74)	41	36
-0.97 (-2.54 to 0.60)	8	8
-0.70 (-1.32 to -0.08)	14	14
-0.60 (-0.75 to -0.45)	244	241
-0.68 (-0.81 to -0.54)	-	-

Study, Year (Reference)

- Kordonouri et al, 2010 (52)
- Deiss et al, 2006 (58)
- Tamborlane et al, 2008 (56)‡
- Mauras et al, 2012 (60)
- Tamborlane et al, 2008 (56)†
- Beck et al, 2009 (54)
- Tamborlane et al, 2008 (56)*
- Hirsch et al, 2008 (57)
- Racah et al, 2009 (53)
- O'Connell et al, 2009 (55)
- Battelino et al, 2011 (59)
- Overall

Pooled OR for Severe Hypoglycemia



OR (95% CI)

Events, n/N
rt-CGM SMBG

0.00 (0.00-2.0e plus 23.00)	0/76	4/78
0.00 (0.00-7.7e plus 23.00)	0/52	1/48
0.53 (0.12-2.35)	3/57	5/53
0.57 (0.13-2.46)	3/73	5/71
0.67 (0.18-2.50)	4/56	6/58
0.92 (0.30-2.78)	7/67	7/62
1.12 (0.28-4.44)	5/52	4/46
4.83 (0.99-23.63)	8/66	2/72
1112.22 (0.00-9.5e plus 29.00)	1/55	0/60
(Excluded)	0/26	0/29
(Excluded)	0/62	0/58
0.88 (0.53-1.46)	-	-



Accu-Chek Spirit Combo Pump



- Remote meter (Accu-Chek Aviva Plus meter)
 - Can bolus from meter or pump
 - Color screen meter
- Basal increments of 0.01 u/hr & bolus increments of 0.05 u
- Intuitive set-up within time segments
- Options for personalizing pump dosing

Animas Vibe & Ping Pumps



- Vibe is display for the Dexcom G4
- Ping: B&W remote(One Touch Ultra)
 - Can bolus discretely
 - Can bolus w meter& pump
- Basal increment of 0.025 u & bolus increment of 0.05 units
- Color pump screen
- IPX 8: waterproof-12 ft x 24 hours
- IOB clearly visible on Ping when glucose is tested for a bolus; on Vibe CGM screen and w/bolus

Medtronic 530 G Pump



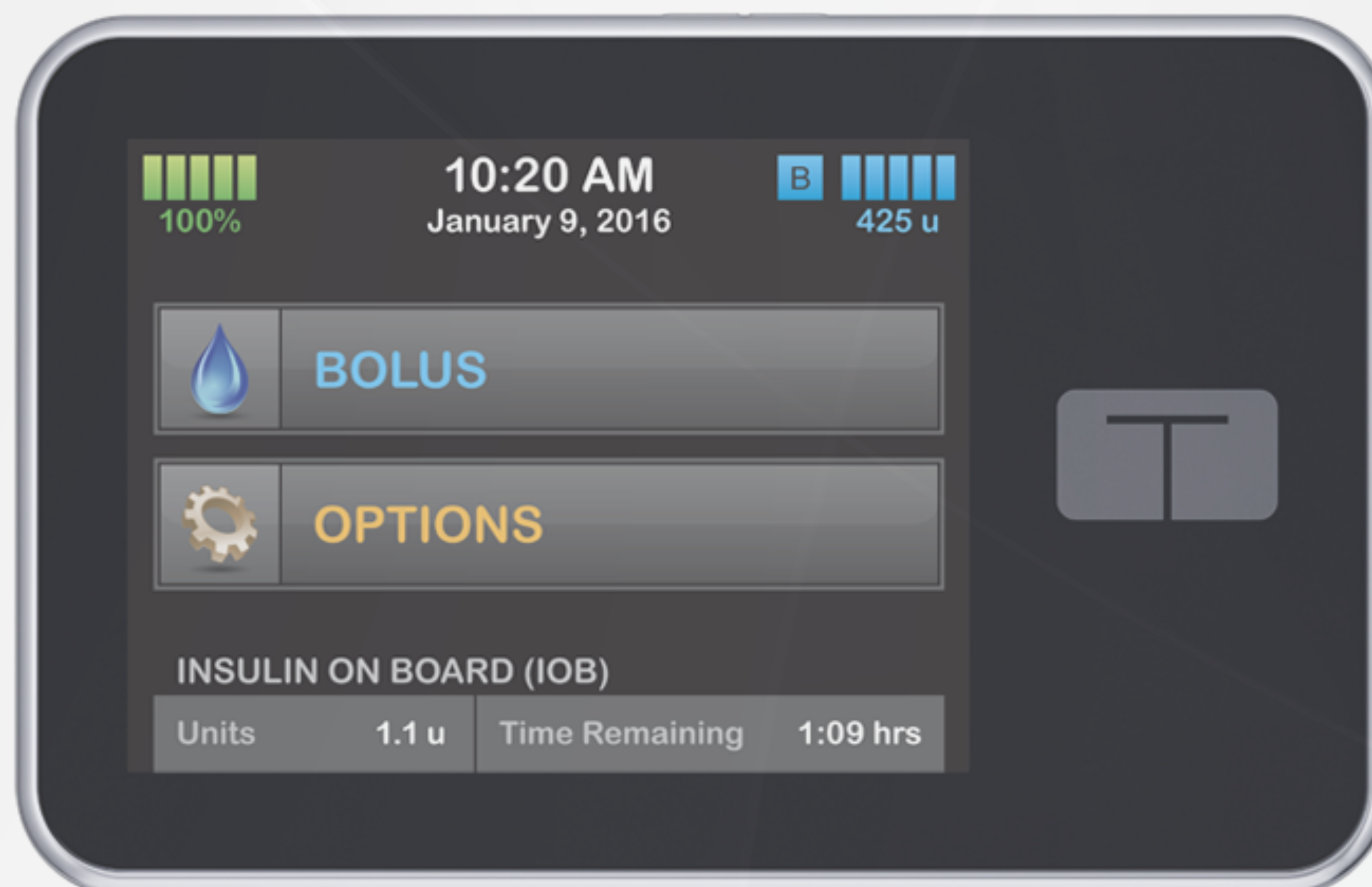
- The Threshold Suspend automatically stops insulin delivery when sensor glucose values reach a preset low threshold.
- Bayer Contour Next meter with color screen sends data to pump
- CGM data visible on pump
- Integrated CGM has different glucose alerts by time of day
- CareLink[®] online data reports
- Basal increments of 0.025 u/hr; Bolus increments of 0.05u
- Good history in pump with data averaged for 2 to 30 days

Insulet OmniPod Pump



- Discreet patch pump with strong adhesive
- Automated insertion of 6.5 mm angled Teflon catheter
- Able to access unique sites because cannula inserted hands-free
- Glooko, Inc[®] online reports
- Basal increments of 0.001 u/hr; bolus increments of 0.05 u
- Good history with data averaged for 1 to 90 days
- No disconnect for bathing, swimming, etc.— no insulin interruption

Tandem t: slim, t: flex



- t:slim G4 displays Dexcom G4
- T:flex holds up to 480 units
- Color touch-screen
- Basal increment of 0.001; Bolus increments of 0.01
- Easy to train and use
- IOB visible on home screen
- Good history in pump with data averaged over 7, 14, or 30 days
- Up to 72 hour duration for a temporary basal

Valeritas V-Go



- Covered as a pharmacy benefit
- Disposable (change every 24 hrs)
- No battery—mechanical spring
- Patch pump
- ↓ \$ pump for T2DM patients
- Pre-set basal rates:
 - V-Go 20 (0.83 u/h basal) + 36 u (2u increment bolus)= 56 u
 - V-Go 30 (1.25 u/h basal) + 36 u (2u increment bolus)= 66 u
 - V-Go 40 (1.67 u/h basal) +36 u (2u increment bolus)= 76 u

Enhanced Features of the Insulin Pumps

- Precise dosing-delivery up to 0.025 units
- Temporary adjustments of basal rates – for illness, activity, etc.
- Insulin Bolus/Carbohydrate Calculations
- Different types of Bolus Delivery:
 - Normal/Standard
 - Square/Extended
 - Dual/Combination – delivers a normal bolus followed by an extended bolus; good for pizza, Chinese foods, high fat foods



Choosing the Right Type of Bolus

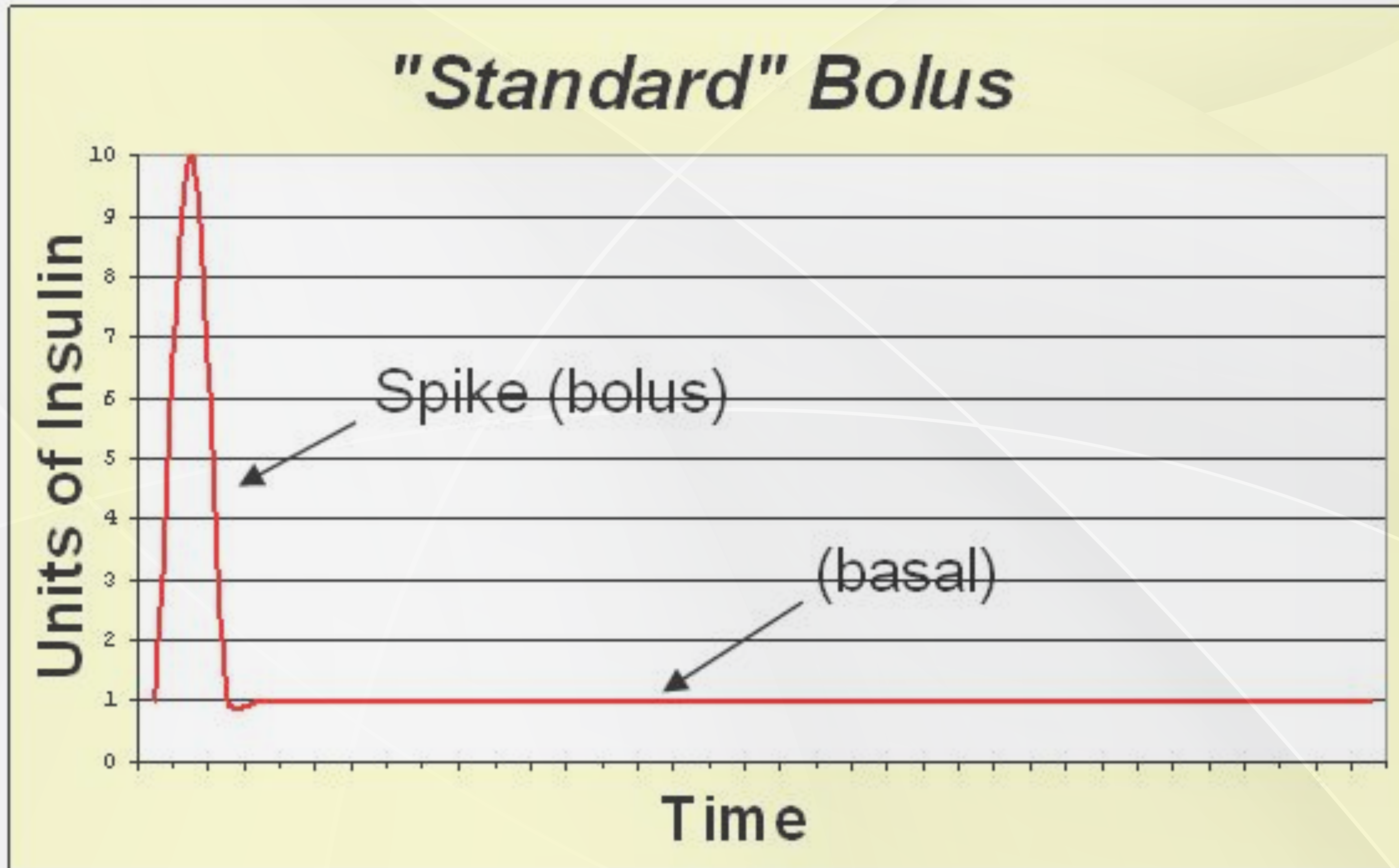
Normal or standard bolus: Pump delivers insulin all at once; used for most meals.

Extended or Square bolus: Pump delivers insulin over a designated time; used for extended meals and gastroparesis.

Combination or Dual Wave bolus: Pump delivers a portion of the bolus as a normal bolus, followed by the remainder as an extended bolus; used for high fat meals.

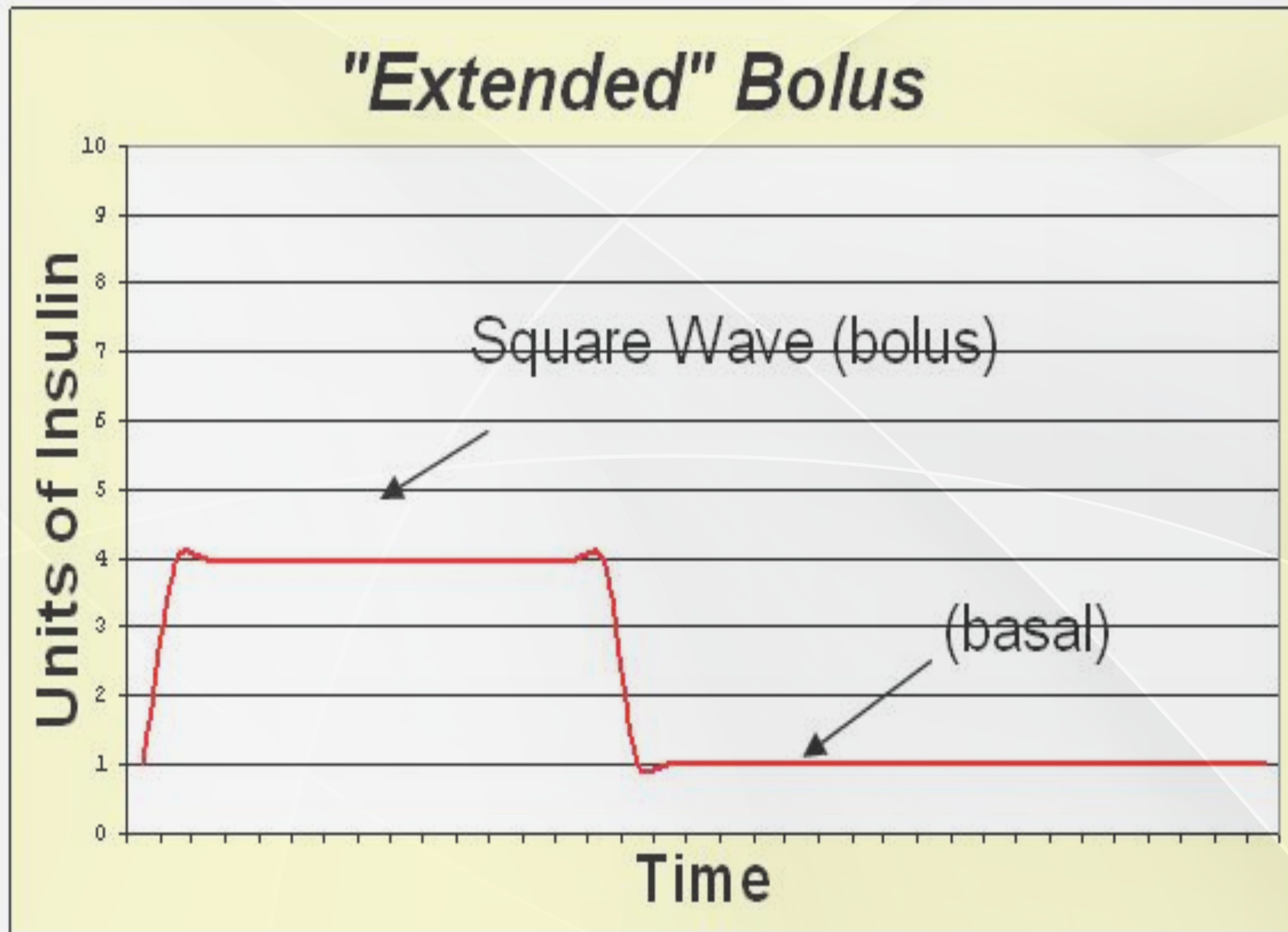


"Standard" Bolus



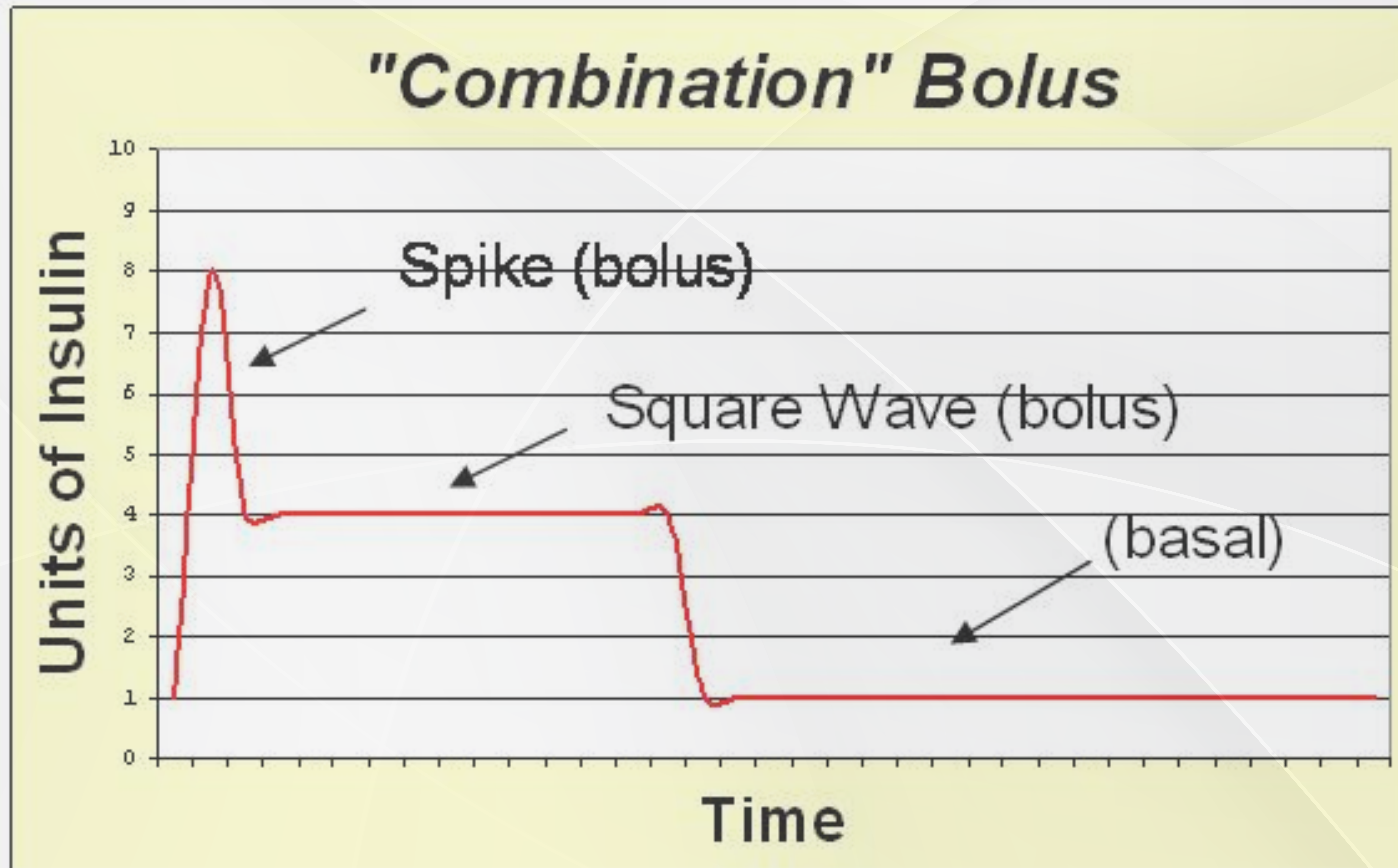
Also known as NORMAL bolus





Insulin delivered evenly over a specified time. Example of usage: Buffet





Standard bolus plus extended bolus.

Example of usage: pizza, Chinese foods, high fat foods.



Self Management Behaviors

- Checking BG ≥ 6 times daily & logging results
- Changing infusion sets every 2-3 days
- Counting carbohydrates
- Testing basal rates by skipping meals
- Testing ICRs and ISFs to get best results
- Determining the duration of insulin action
- Analyzing blood glucose patterns
- Self adjusting rates, and re-checking

Walsh J. & Roberts R. (2006). *Pumping Insulin*.

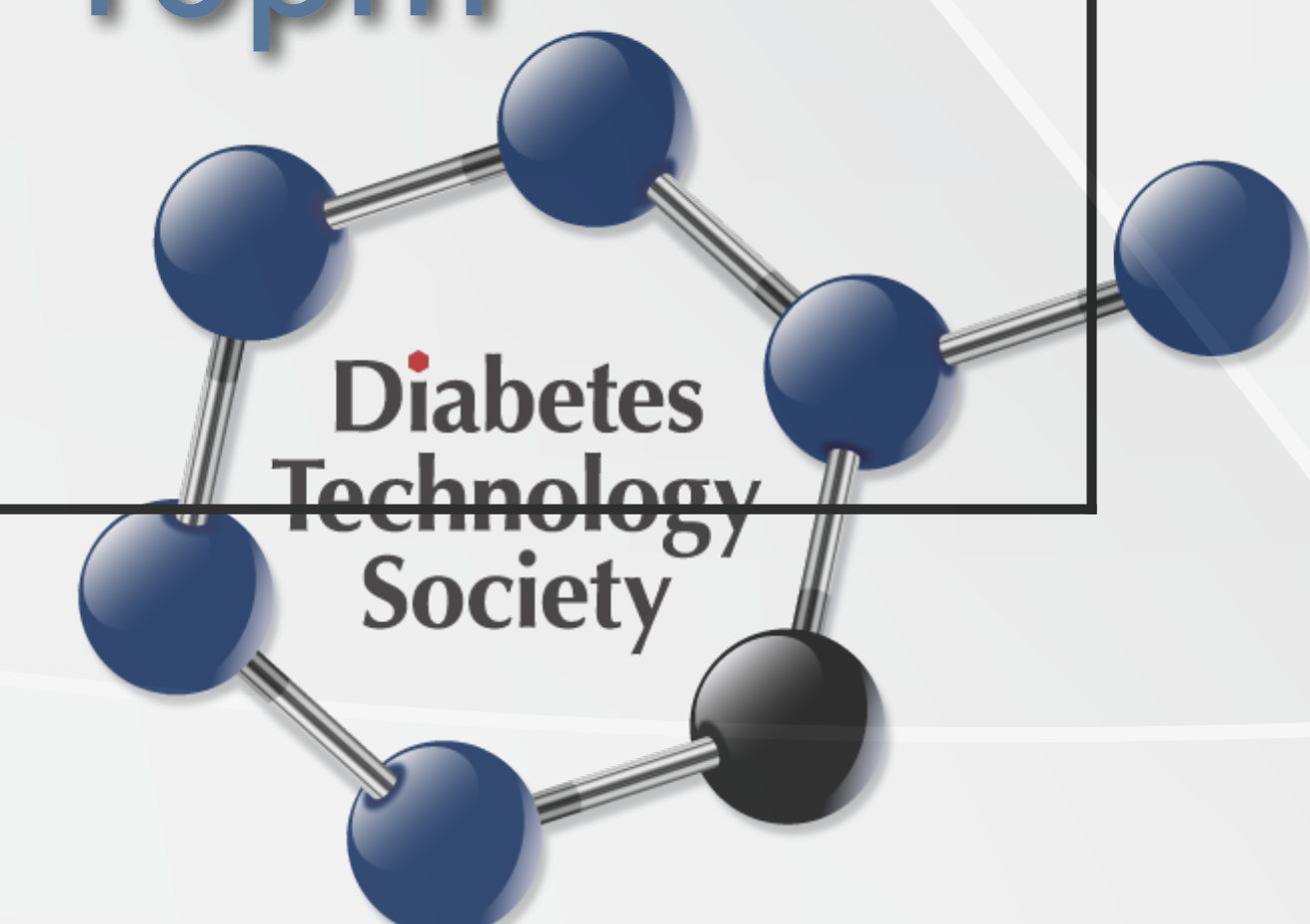
Scheiner G. (2012). *Think like a pancreas: practical guide to managing diabetes with insulin*.



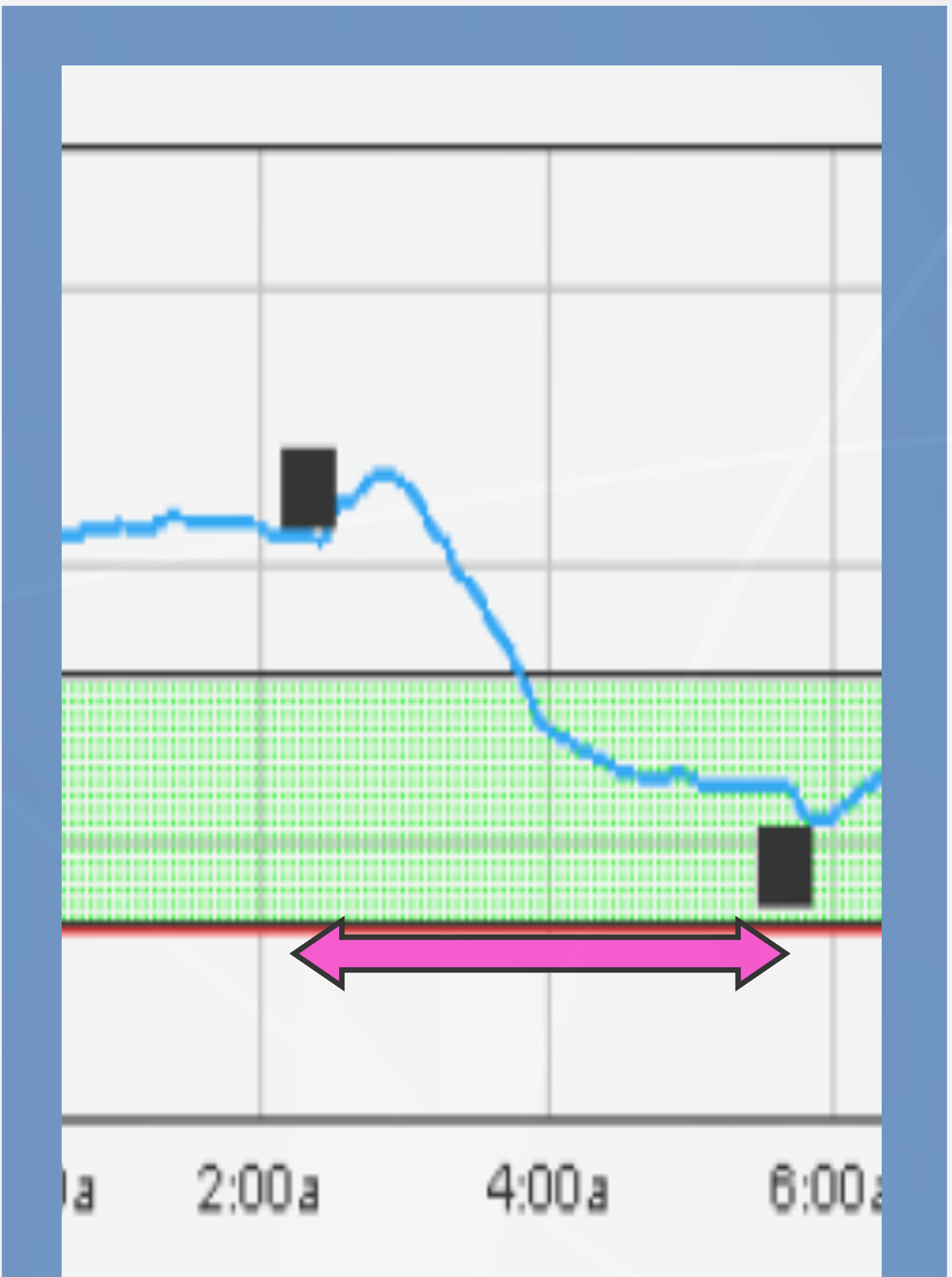
Basal Insulin Regulation

Sample Basal Testing Schedule

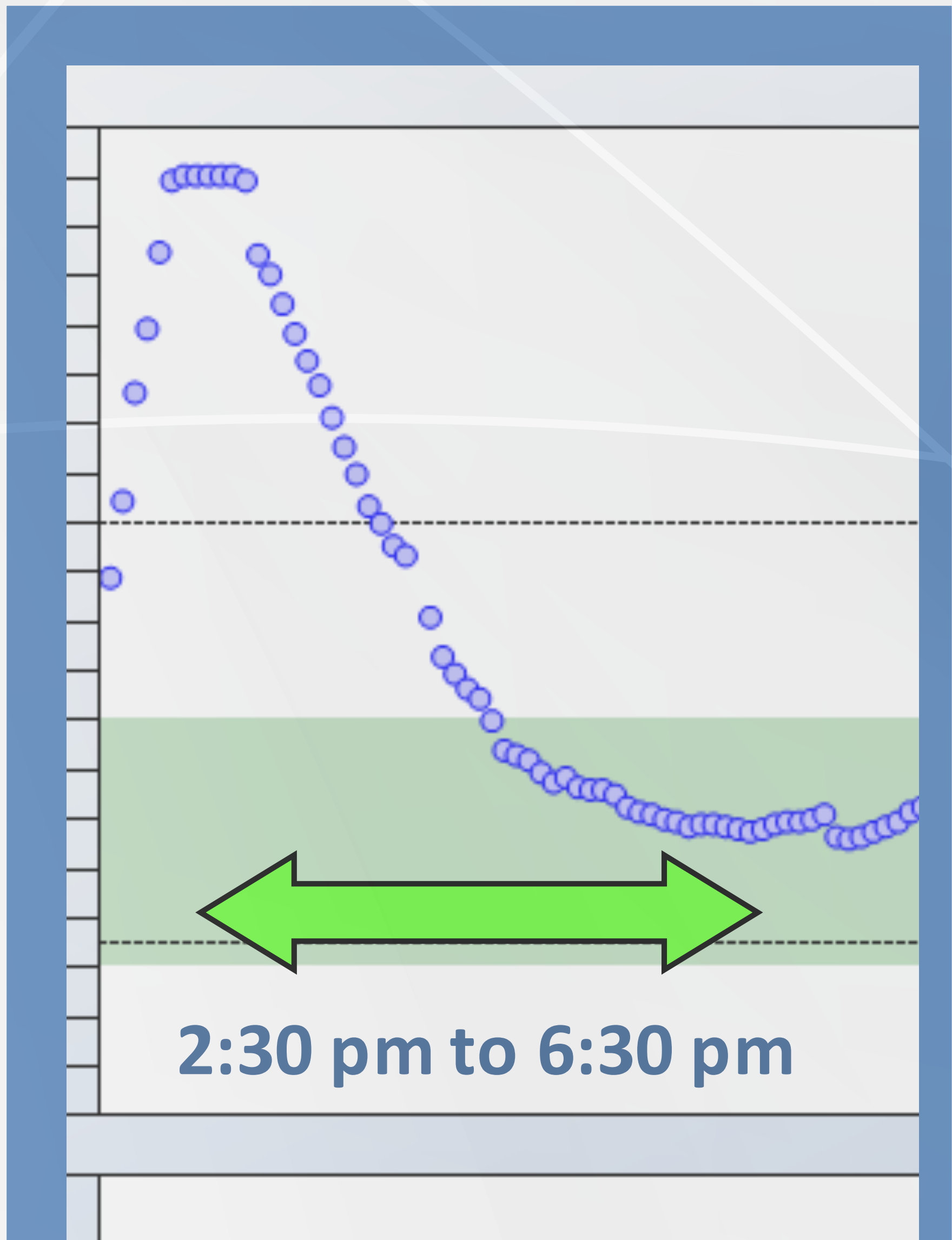
Test	Last Meal / Bolus By	Check BG at	May Eat / Bolus Again at
Overnight	6pm (skip night snack)	10pm, 1am, 4am, 7am	7am
Morning	3am (skip breakfast)	7am, 9am, 11am, 12noon	12 noon
Afternoon	8am (skip lunch)	12 noon, 2pm, 4pm, 5pm	5pm
Evening	1pm (have late dinner)	5pm, 7pm, 9pm, 10pm	10pm



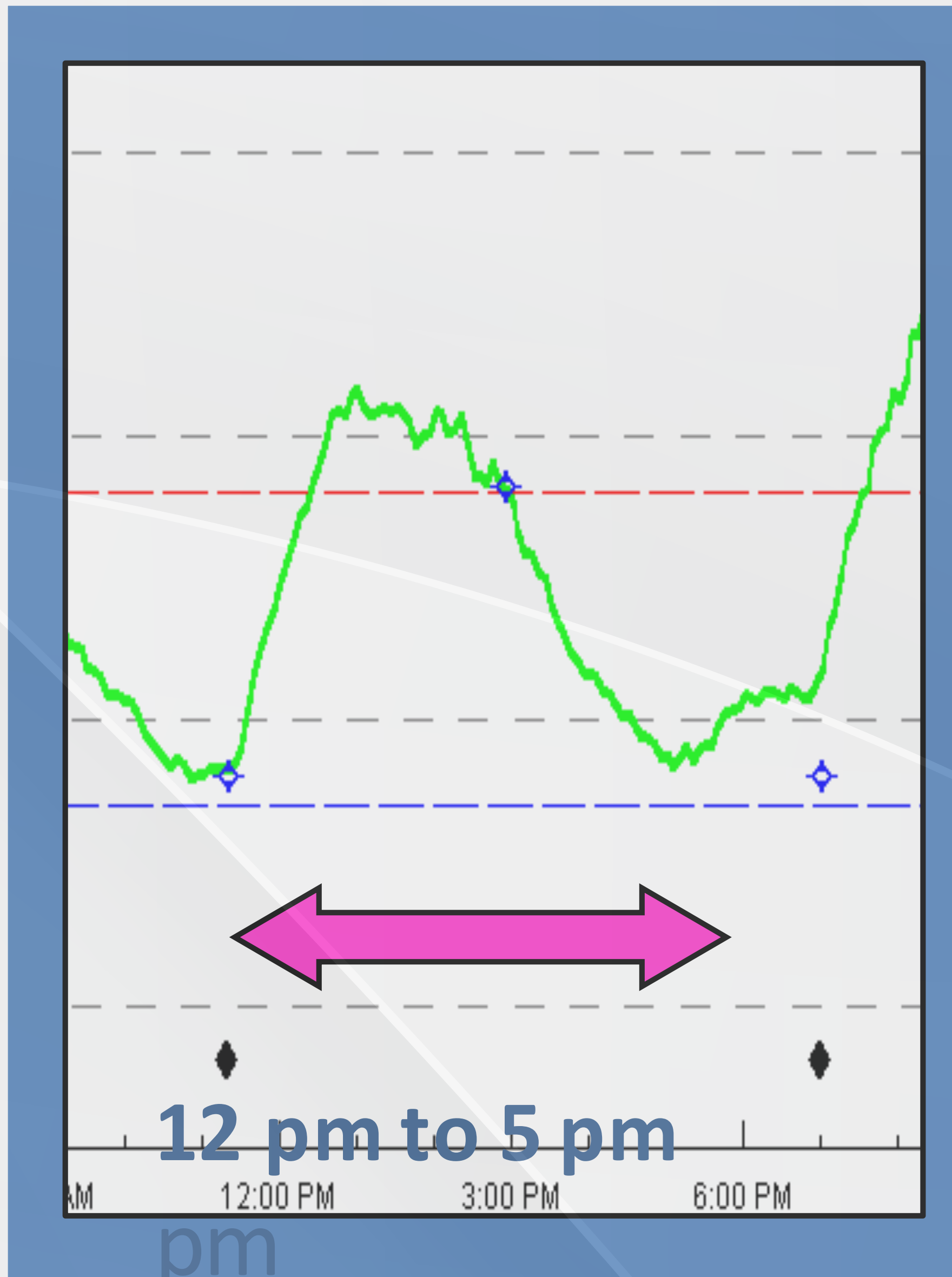
Bolus Insulin Duration: IOB



**3-Hour
Duration**

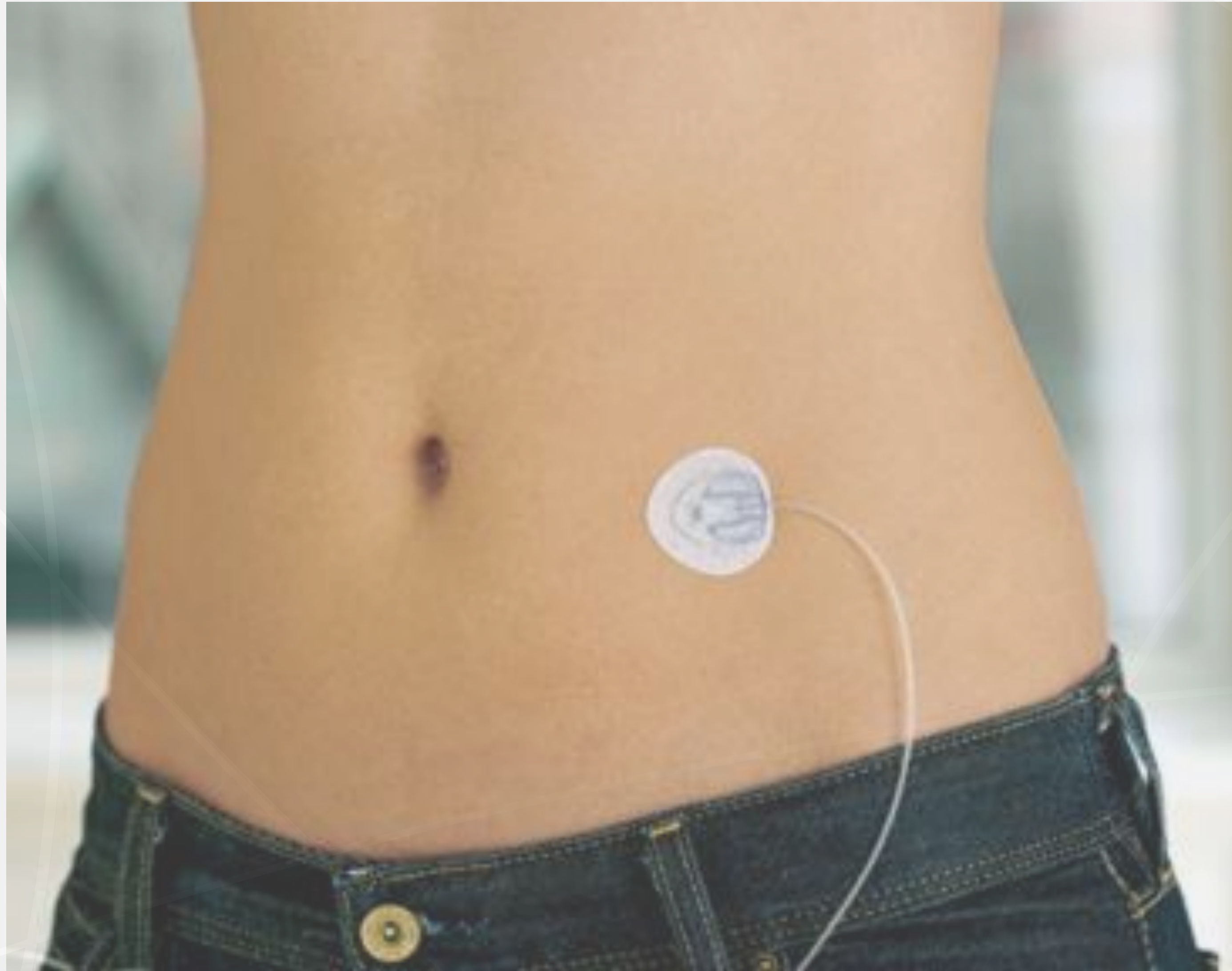


**4-Hour
Duration**



**5-Hour
Duration**

Infusion Site Issues Another Understudied Factor



Why Is It Important To Rotate Insulin Infusion/Injection Sites?



- Maintain healthy tissue
- Decrease scarring
- Improve insulin absorption
- Minimize erratic blood glucoses due to absorption rates
- Infusing into hypertrophied tissue can decrease insulin absorption by 34%

Lipohypertrophy

reference for lipo



Lipohypertrophy (LH) leads to decreased insulin absorption

Diabetes Landmark Studies:

- First glucose clamp study of Lipohypertrophy
- Powered to detect $\geq 20\%$ changes in PK/PD

Euglycemic Clamp Study

- ✓ Insulin absorption is reduced by 34% when injected into LH

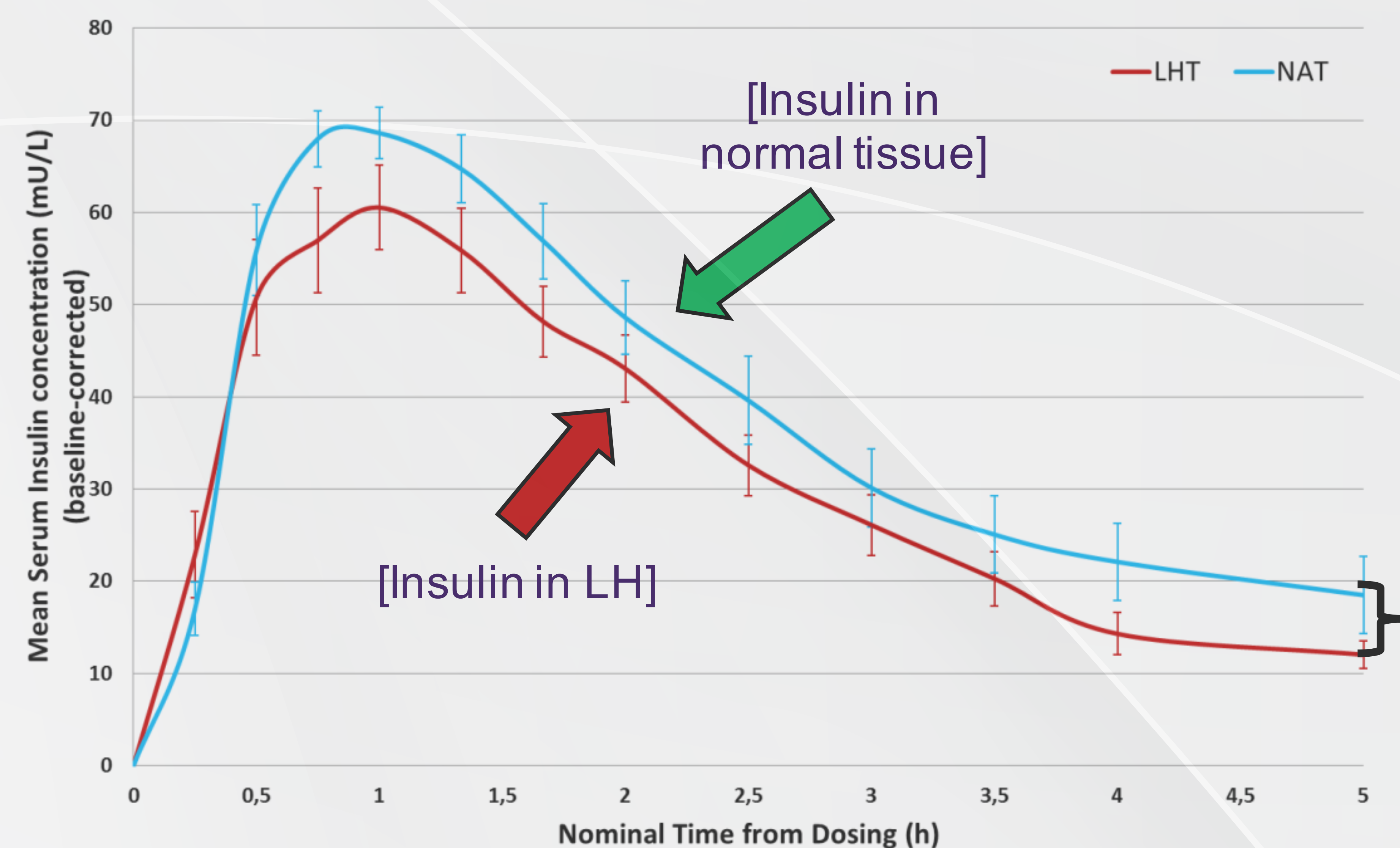


Figure above:

- Baseline-corrected mean serum insulin concentration profiles \pm SEM
- Shows a significant reduction in total insulin exposure thereafter with 34% lower insulin concentration during the first 4 hours after dosing ($p=0.0021$)



Lipohypertrophy (LH) leads to decreased insulin absorption

Diabetes Landmark Studies:

- First glucose clamp study of Lipohypertrophy
- Powered to detect $\geq 20\%$ changes in PK/PD

Euglycemic Clamp Study

- ✓ Insulin absorption is reduced by 34% when injected into LHT
- ✓ PD effect in the first 4 hrs is 27% lower when injecting insulin into LHT

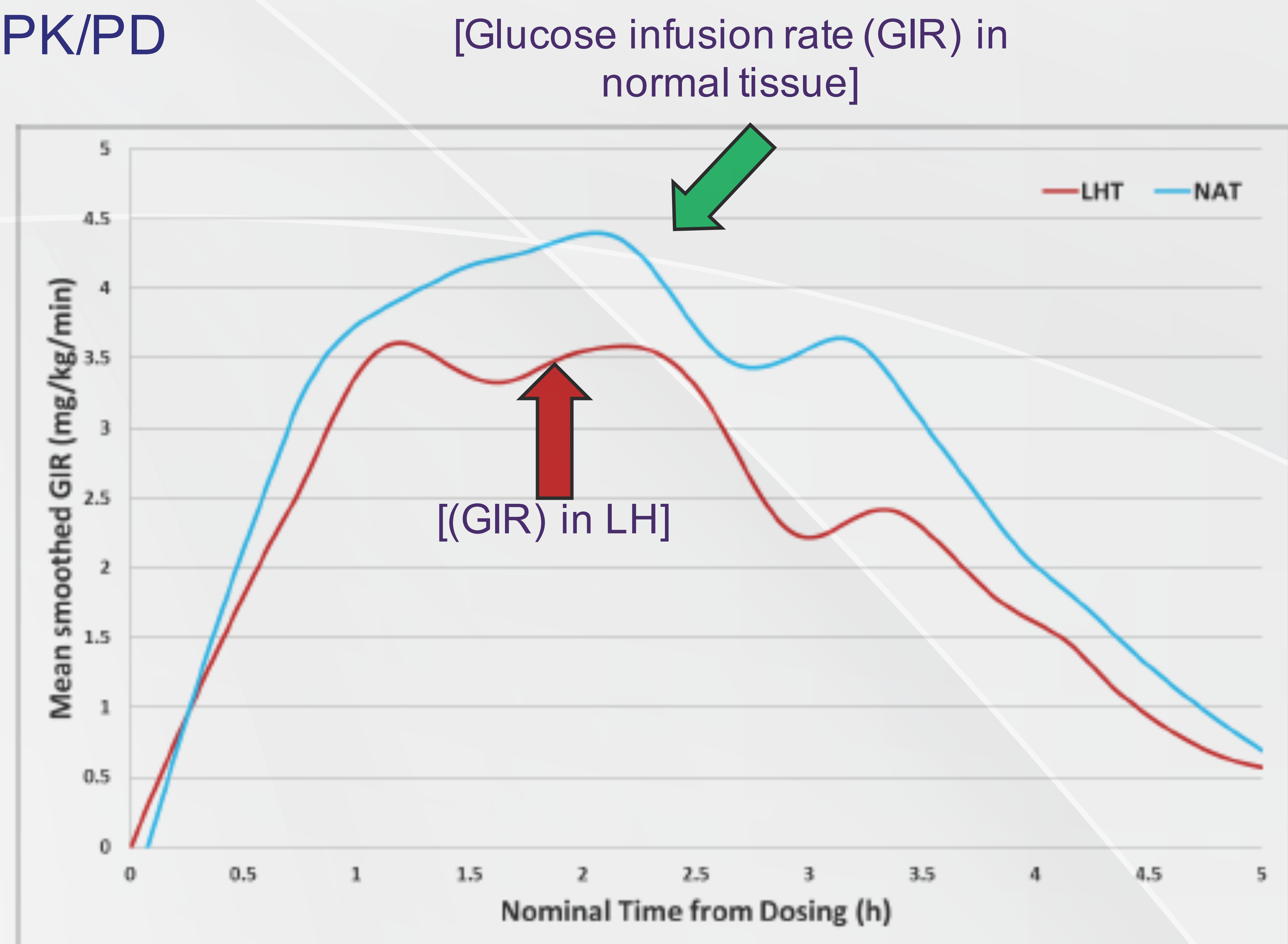
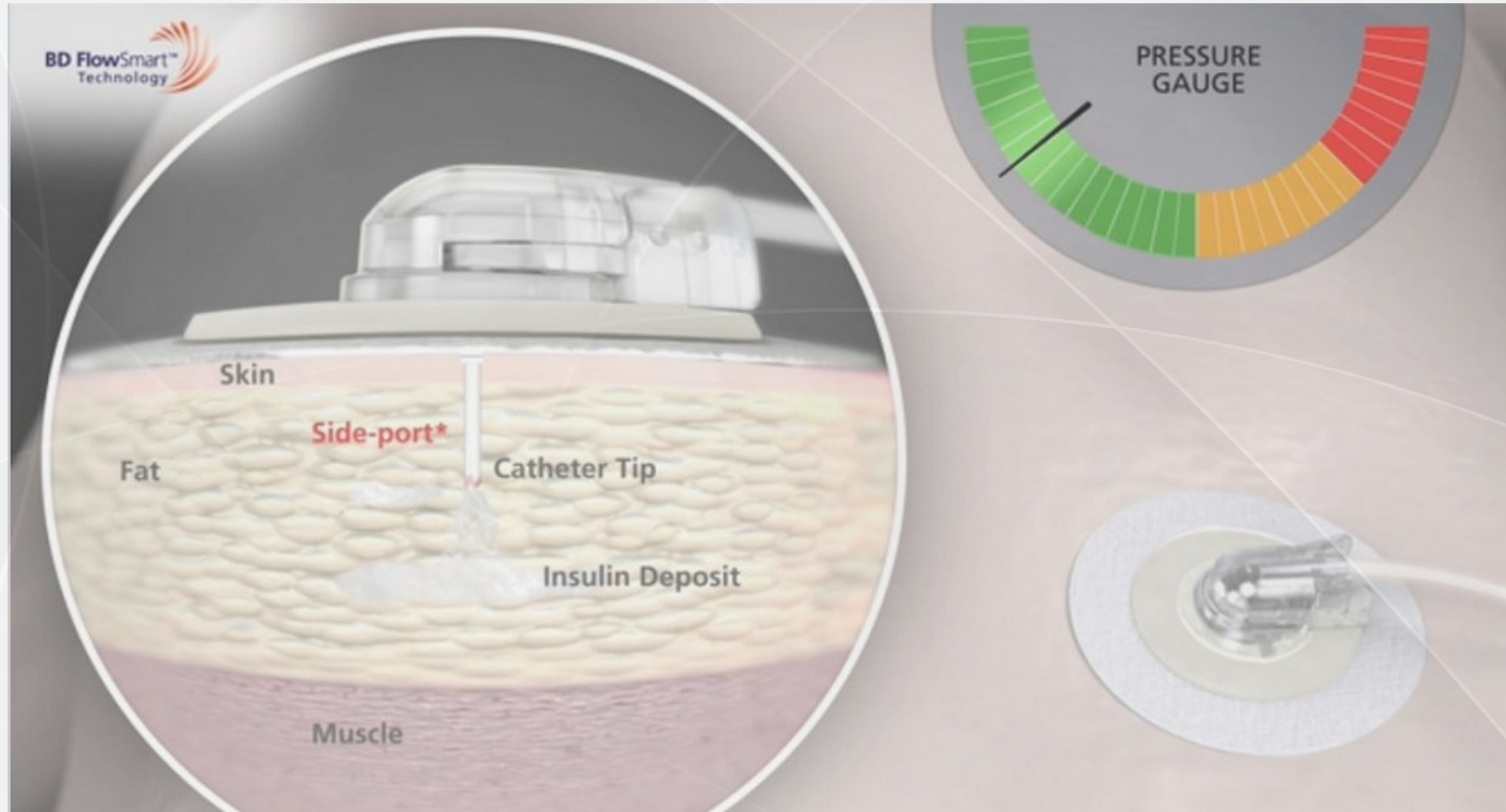


Figure above:

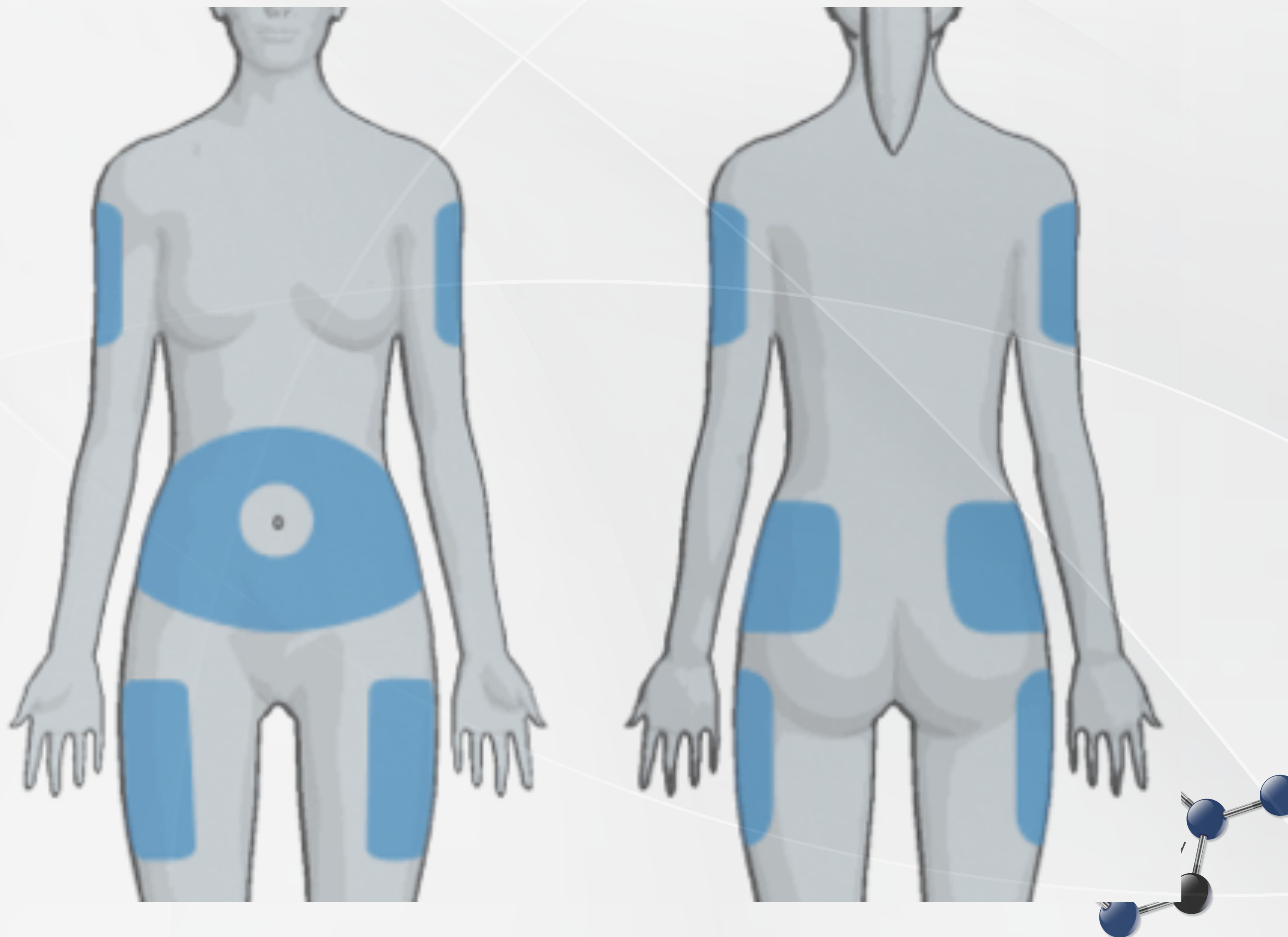
- Mean smoothed glucose infusion rate profiles with LOESS smoothing (smoothing parameter = 0.3)
- GIR profiles show a significant difference in the PD effect from 4 hours after dosing with a reduction in GIR of 27% ($p=0.0390$)



BD Flow Smart Technology



Pump Infusion Sites



The Quest

- The quest for “virgin territory” is frequently the greatest challenge in long-term insulin pump use.
- Varying the infusion sets between 90 degrees and 45 degree oblique insertions may help place cannulas in slightly different areas.
- Develop a systematic approach to site rotation.
- As HCPs, we **MUST** inspect infusion sites at every visit



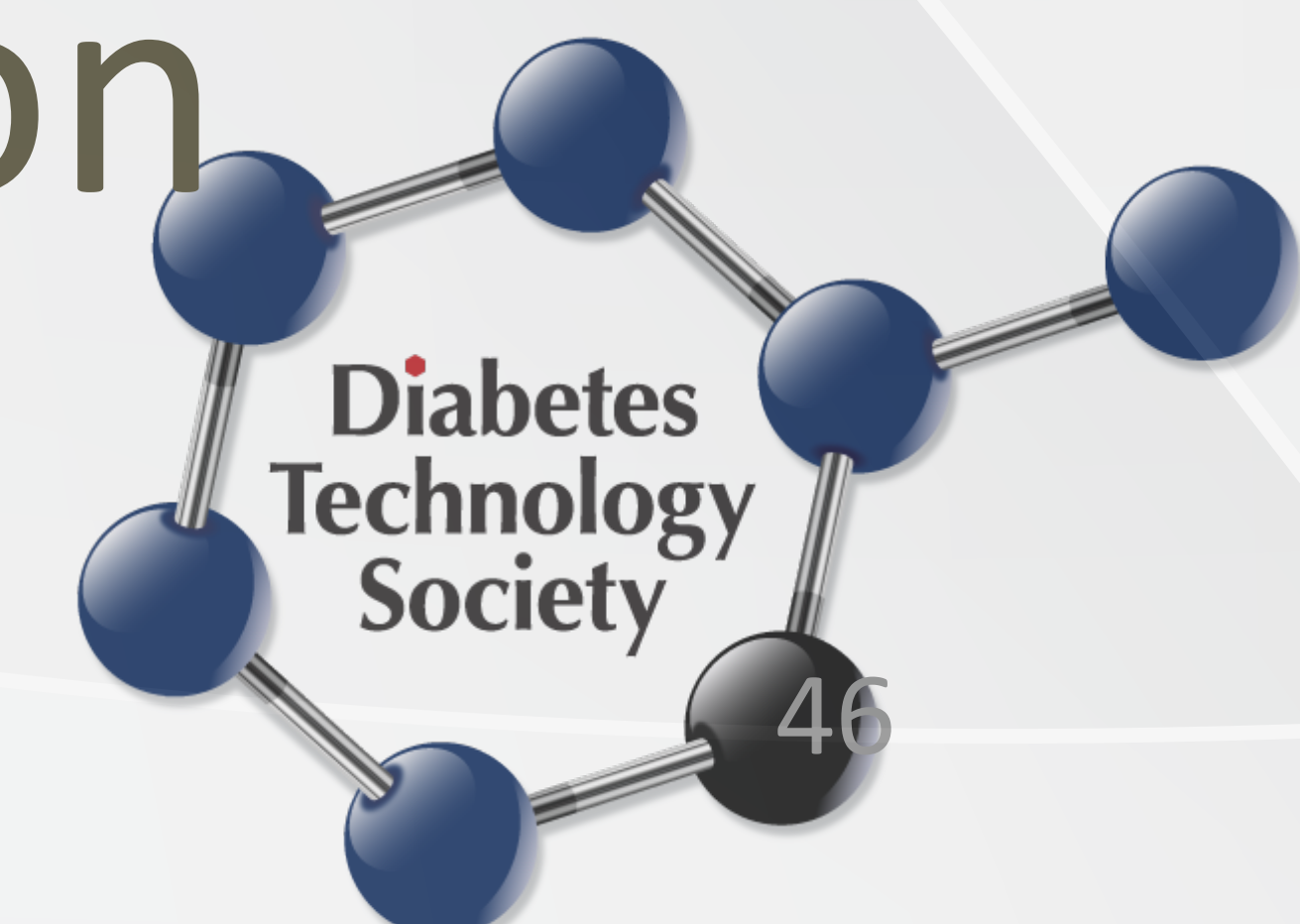
Safe Hospital Use of Insulin Pumps

- Written Policy as Guide
- Endocrine consult
- Order Set: 'Pt. may use own pump'
- Pt. attestation to agree to **self** management
- Pt. brings own pump supplies
- RN documents meal boluses, infusion site changes, and inspection of sites every shift
- Hospital Insulin
- Hospital BG Meter



When to D/C Pump

- Critically ill, septic, trauma
- Altered state of consciousness
- Depressed/suicidal
- Requires insulin drip
- Pt. or caregiver unwilling/unable to perform self management
- Unwilling to sign attestation
- Radiology, MRI, procedures w/sedation



What Questions Do You Have?

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