DIABETES TECHNOLOGIES

How is technology helping improve outcomes?

Sophia Ebenezer, MD

February 6, 2021

Texas Children's Hospital

2021 Virtual Diabetes Management Conference for School Nurses

Provided by Texas Children's Hospital

NURSING CONTINUING PROFESSIONAL DEVELOPMENT (NCPD)

Texas Children's Hospital is approved with distinction as a provider of nursing continuing professional development (NCPD) by the Texas Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

REQUIREMENTS FOR SUCCESSFUL COMPLETION

To receive contact hours for this nursing continuing professional development activity, the participant must:

- Register for the continuing professional development activity
- Attend at least one session
- Complete a pre and post survey
- Complete a participant evaluation online

Print and sign your contact hour "Certificate of Successful Completion" once you have completed the online evaluation.

LEARNING OUTCOME

As a result of this professional development activity, 90% attendees will intend to integrate what they have learned into their professional practice and be able to name one concept learned on the post activity evaluation.

CONFLICTS OF INTEREST

Explanation: A conflict of interest occurs when an individual has an opportunity to affect or impact educational content with which he or she may have a commercial interest or a potentially biasing relationship of a financial nature. All planners and presenters/authors/content reviewers must disclose the presence or absence of a conflict of interest relative to this activity. All potential conflicts are resolved prior to the planning, implementation, or evaluation of the continuing nursing education activity. All activity planning committee members and presenters/authors/content reviewers have had their Conflict of Interest assessed, identified and resolved by the nurse planner.

The activity's Nurse Planner has determined that the following planning committee member(s) and/or presenter(s)/author(s)/content reviewer(s) have a conflict of interest. Those conflicts of interest have been appropriately resolved.

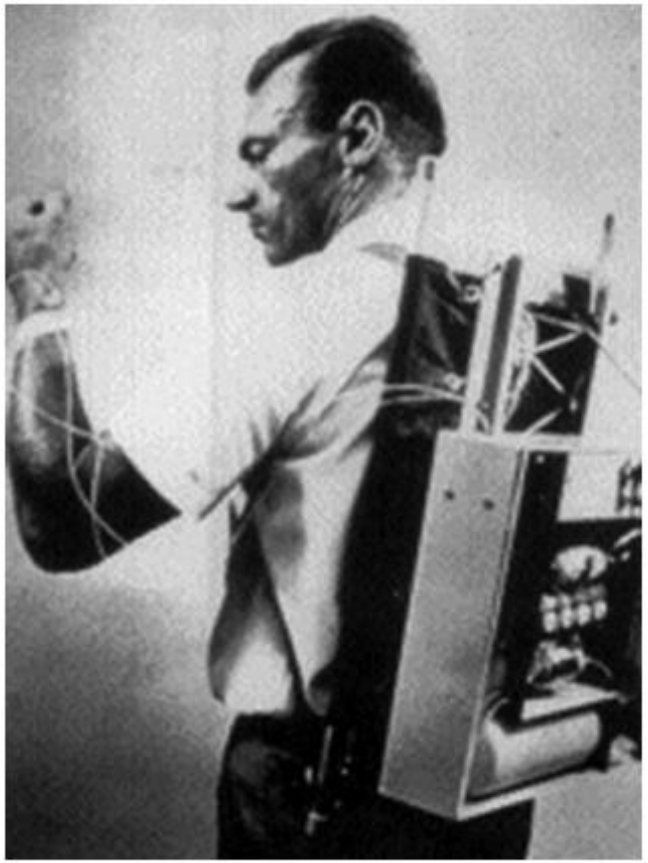
- Planning Committee - Amber Smith – Ownership Interest in Tandem Diabetes Care

COMMERCIAL SUPPORT

This NCPD activity has received no commercial support.

OBJECTIVES

- Upon completion, participant will be able to discuss:
  - Discuss how insulin pump therapy works
  - Discuss the current FDA-approved and commercially available CGM devices and insulin pumps
  - Discuss closed loop systems
  - Discuss future directions of diabetes devices



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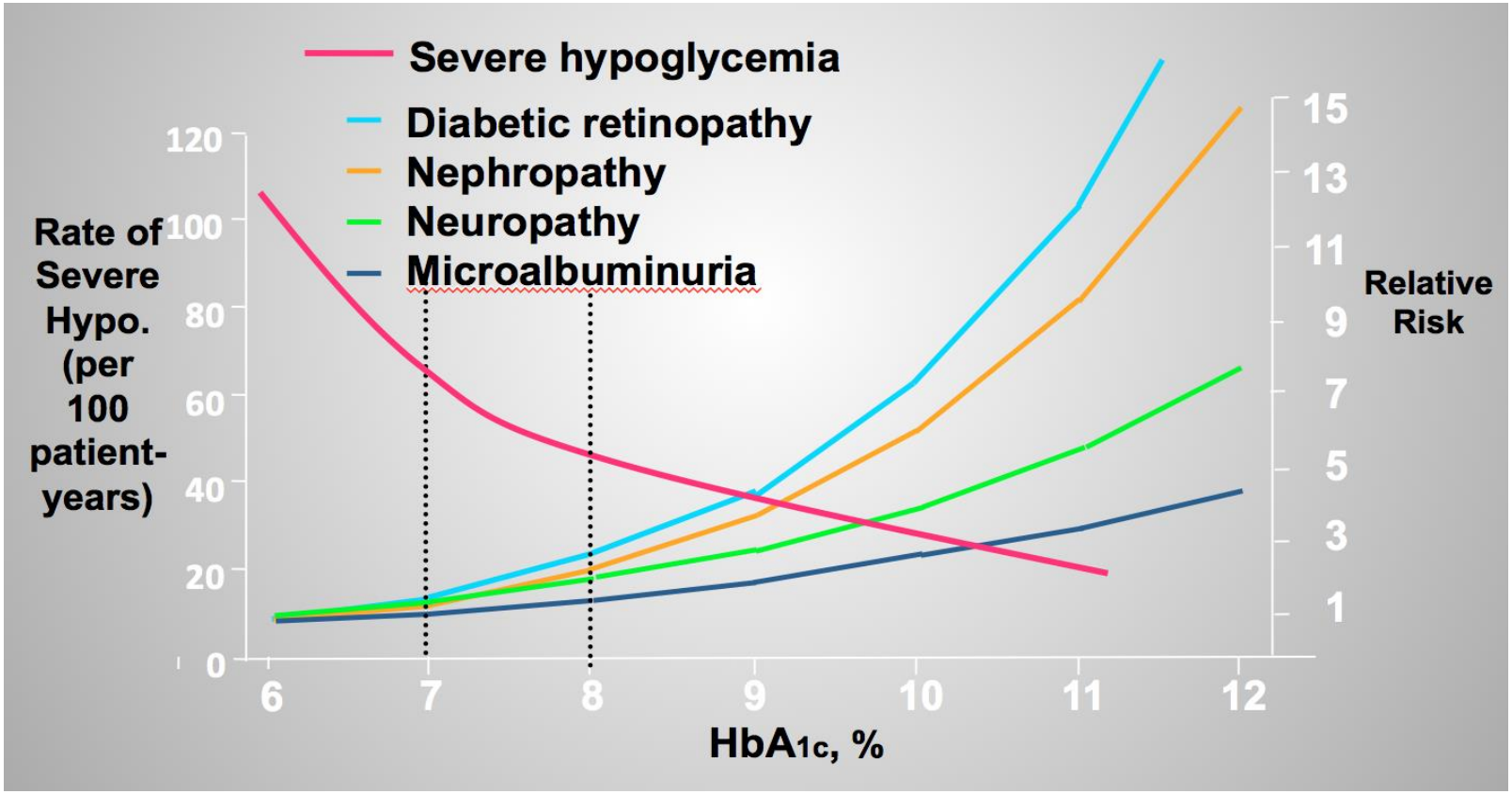
DCCT – BENEFITS OF TIGHT CONTROL

Lower A1c = lower risk of microvascular complications



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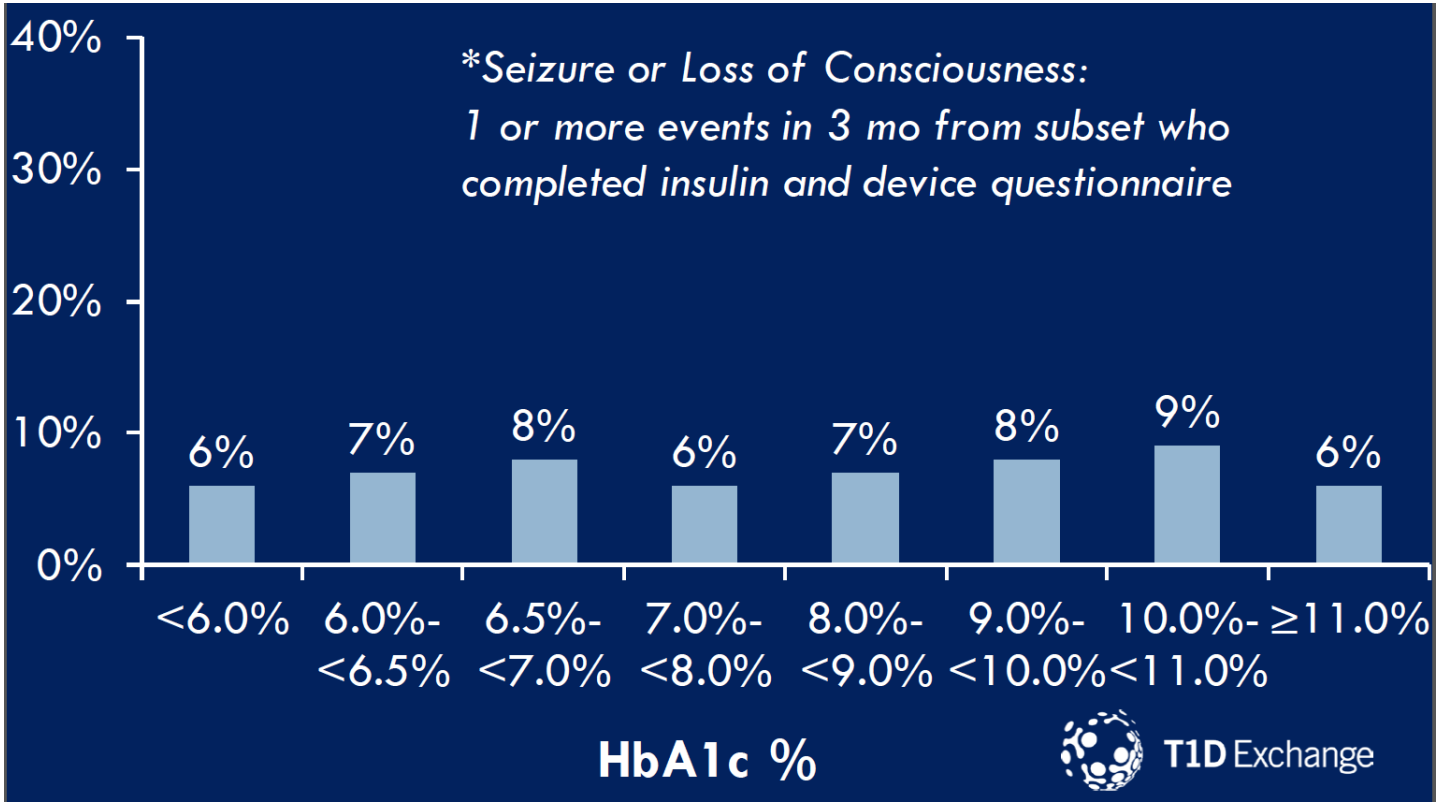
DCCT Research Group. *N Engl J Med,* 1993.
Slide courtesy of Daniel Desalvo, MD

RELATIONSHIP OF A1C TO SEVERE HYPO RISK

In contrast to early DCCT data, no relationship between A1c and severe hypoglycemia



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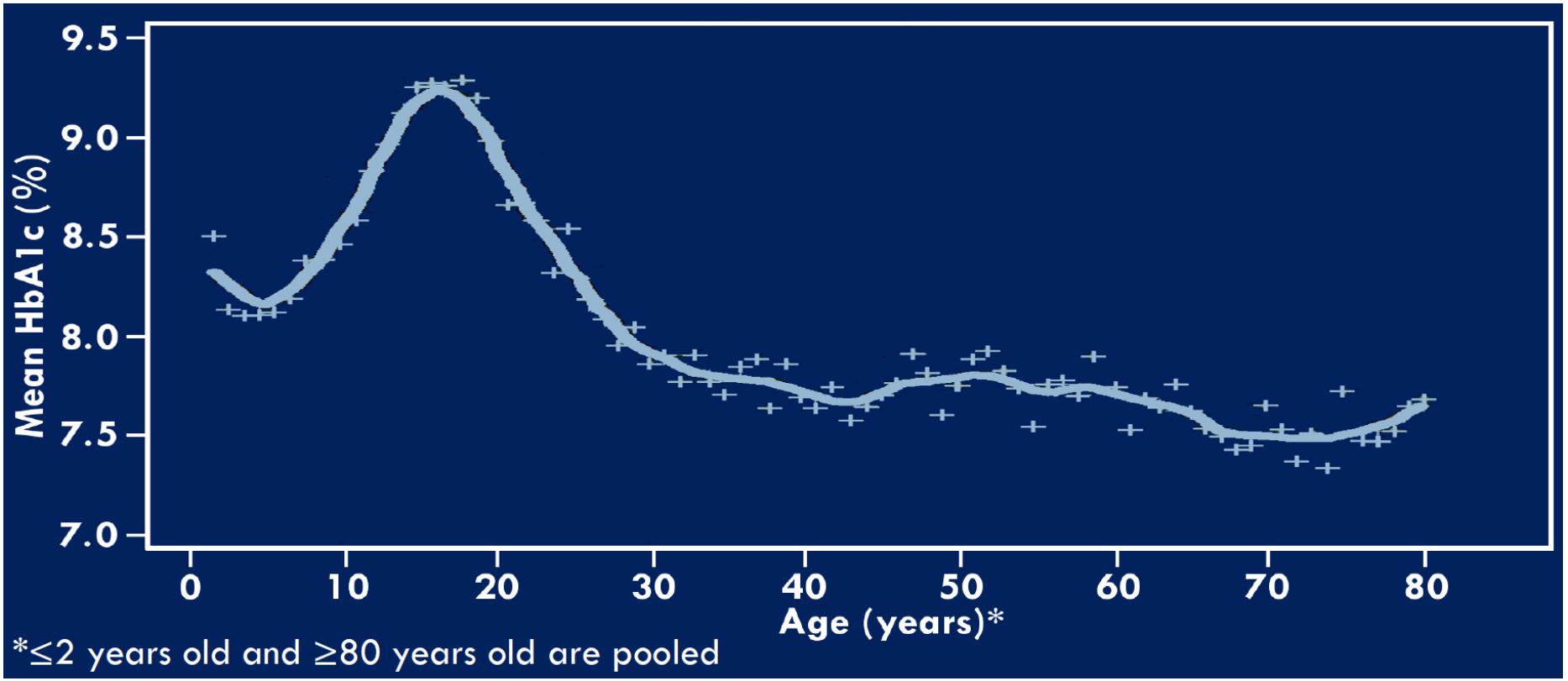
T1D Exchange Clinic Registry data thru March 31, 2018
Slide Courtesy of Daniel Desalvo, MD

HOW ARE WE DOING IN DIABETES CARE?



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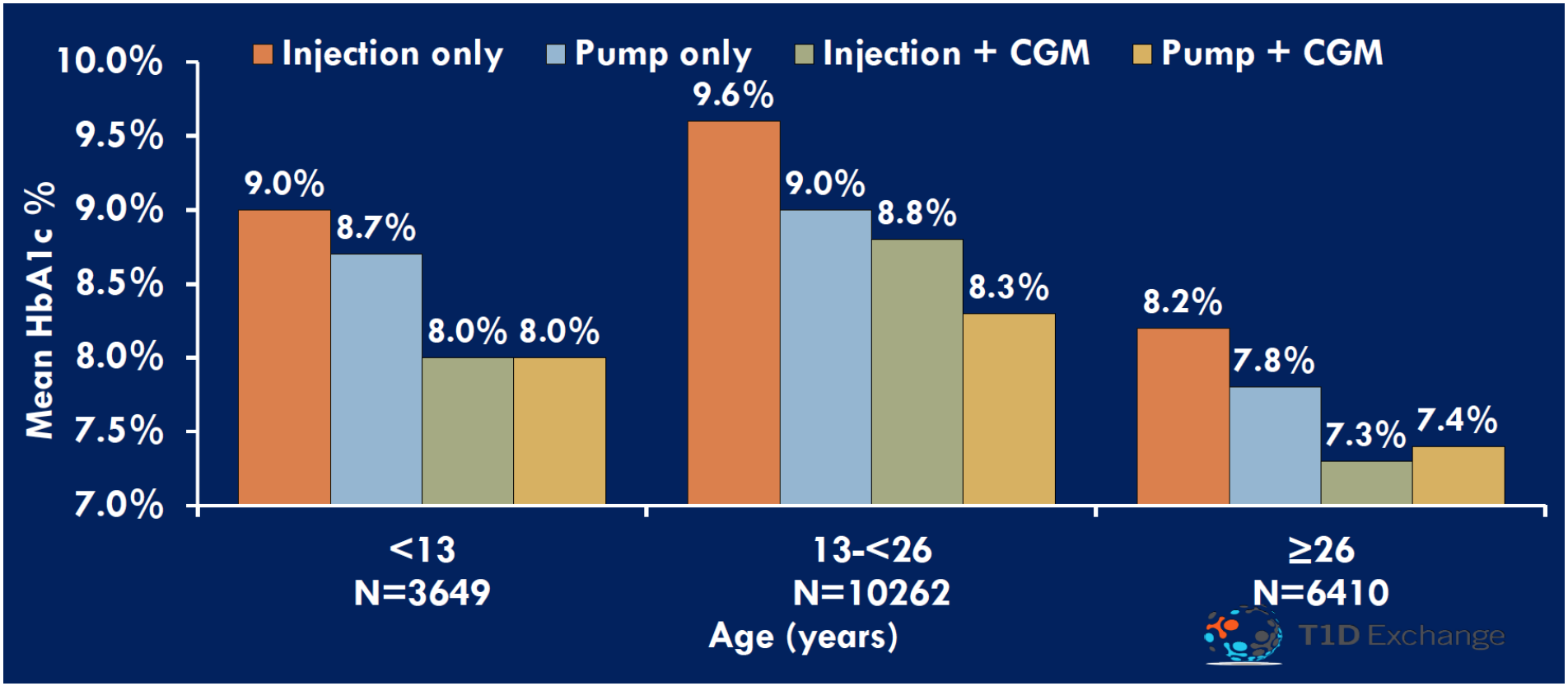
T1D Exchange Clinic Registry data thru March 31, 2018
Slide Courtesy of Daniel Desalvo, MD

LOWER A1C WITH TECHNOLOGY



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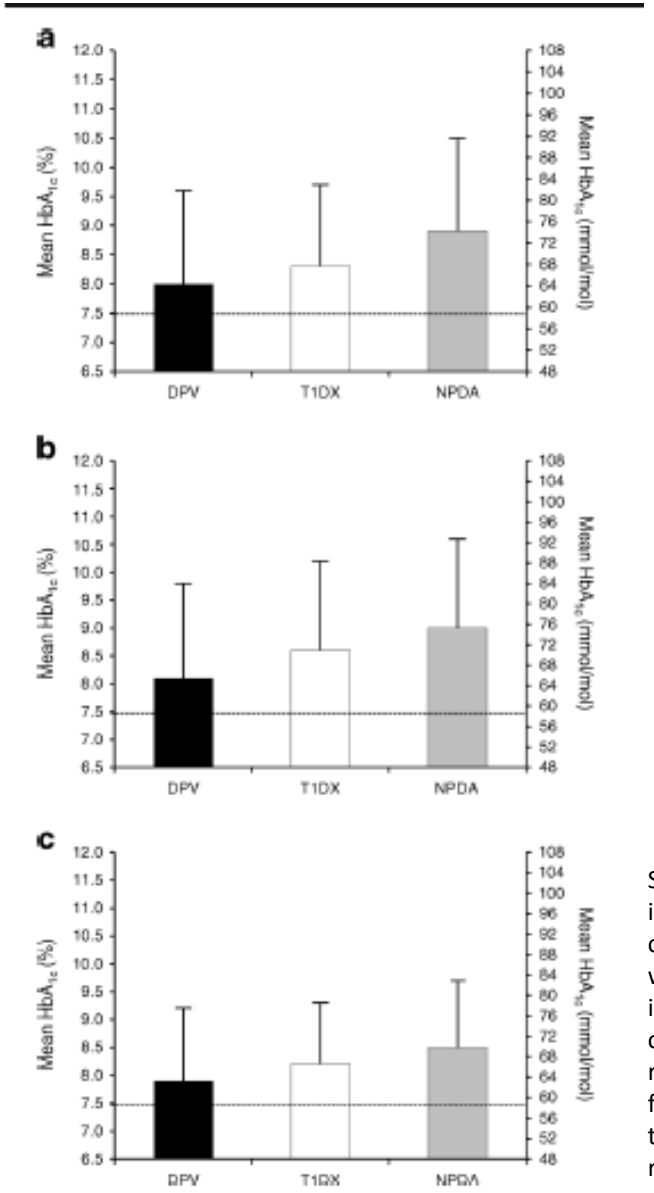
T1D Exchange Clinic Registry data thru March 31, 2018
Slide courtesy of Daniel Desalvo, MD

BENEFITS OF PUMP

HbA1c levels were on average 0.5% lower in participants receiving insulin pump vs injection therapy



Sherr, J. L. et al. Use of insulin pump therapy in children and adolescents with type 1 diabetes and its impact on metabolic control: comparison of results from three large, transatlantic paediatric registries.

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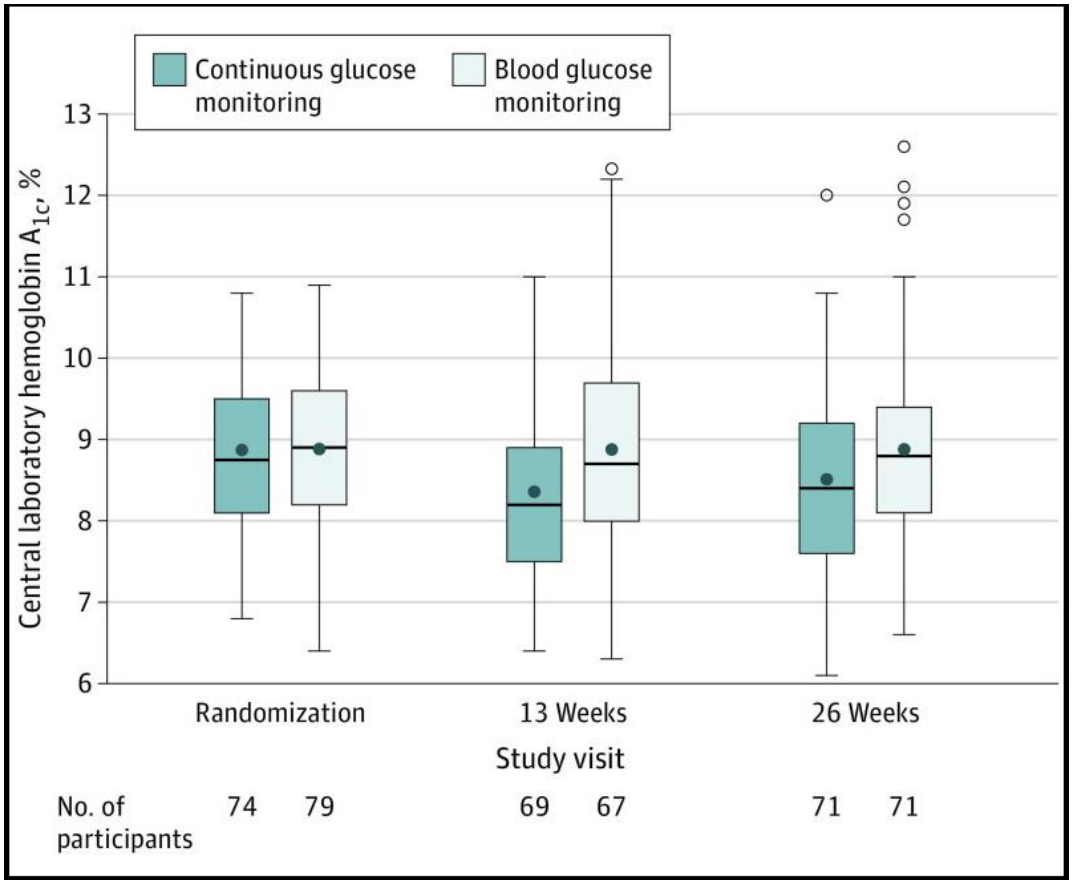
BENEFITS OF CGM

Small but statistically significant lowering of HbA1c over 26 weeks of CGM use compared with standard BGM



Laffel, Lori M et al. "Effect of Continuous Glucose Monitoring on Glycemic Control in Adolescents and Young Adults With Type 1 Diabetes: A Randomized Clinical Trial."

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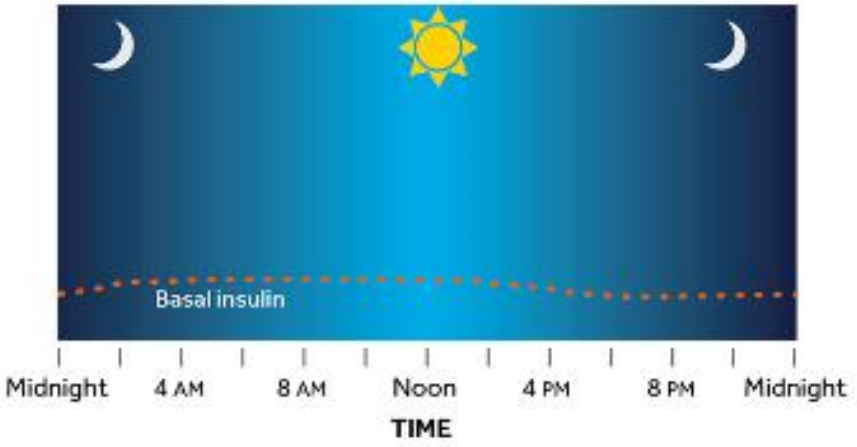
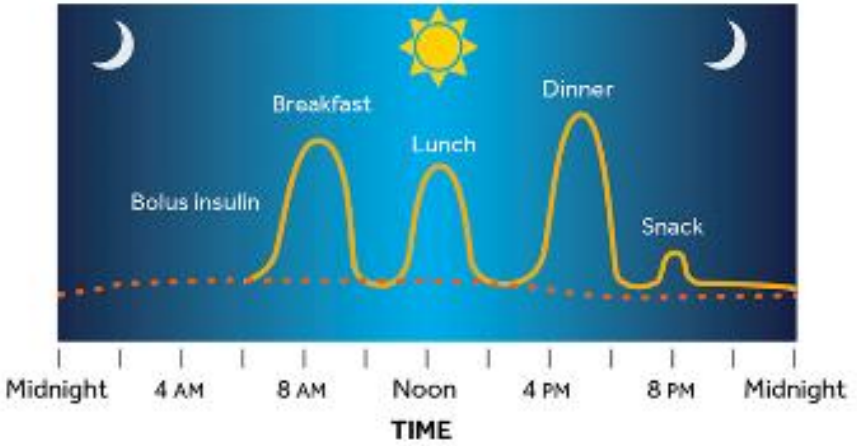
WHAT IS AN INSULIN PUMP?

- A device that delivers continuous rapid acting insulin 24 hours a day
- Basal insulin is released continuously
- Bolus insulin is delivered for meals or high blood sugars





www.medtronicdiabetes.com

HOW DOES AN INSULIN PUMP WORK?

- Insulin is delivered through a cannula in the skin
- May be delivered through tubing or an insulin filled pod

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INDICATIONS FOR INSULIN PUMP THERAPY

AACE/ACE Consensus Statement – 2014

"The ideal CSII candidate is:

- *A patient with T1DM or intensively managed insulin-dependent T2DM,*
- *Currently performing ≥4 insulin injections and ≥4 self-monitored blood glucose (SMBG) measurements daily,*
- *Motivated to achieve optimal blood glucose control,*
- *Willing and able to carry out the tasks that are required to use this complex and time-consuming therapy safely and effectively,*
- *Willing to maintain frequent contact with their health care team."*

Grunberger et al. Endocr Pract. 2014; May;20(5):463-89

ADA Standards of Medical Care in Diabetes – 2020

- *"Insulin pump therapy may be considered as an option for **all** adults, children, and adolescents with type 1 diabetes who are able to safely manage the device."*
- *"Certain patients with **insulin deficiency**, for instance those with long standing **type 2 diabetes**, those who have had a **pancreatectomy**, and/or individuals with **cystic fibrosis** may benefit from insulin pump therapy."*

ADA Standards of Medical Care in Diabetes - 2020. Diabetes Care 2020;43(Suppl. 1):S163–S182

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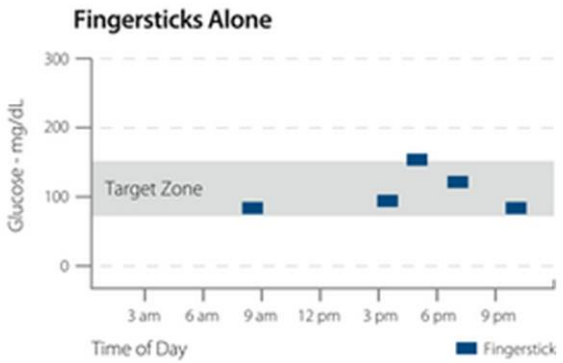
Slide courtesy of Daniel Desalvo,MD

WHAT ARE THE BENEFITS OF AN INSULIN PUMP?

- ✓ Less injections
- ✓ Convenience
- ✓ Accurate insulin delivery
- ✓ Customizable

REVIEW OF GLUCOSE MONITORING

Traditional "fingerstick" glucose testing

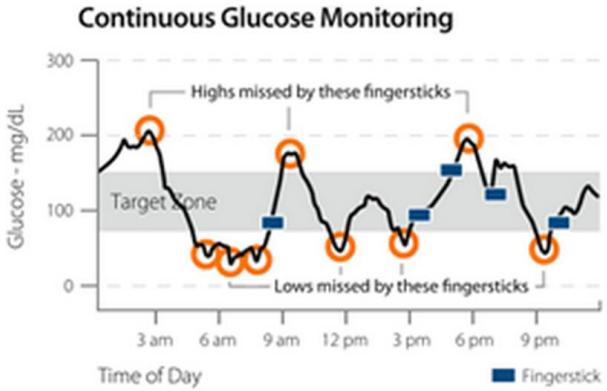


Continuous glucose monitoring (CGM)

A. Sensor

B. Transmitter

C. Display device



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WHO SHOULD USE A CGM AND INTEGRATED SYSTEMS?

AACE/ACE Position Statement – 2018

- *The AACE/ACE recommends that CGM be considered for all insulin-using patients, regardless of diabetes type.*
- *Integration of CGM and CSII may be considered in patients already on CSII or appropriate for initiating CSII.*
- *The ideal candidate for integration must be willing and able to carry out tasks associated with using the system, self-monitor and react to collected data, and maintain frequent contact with the healthcare team.*

WHAT ARE THE BENEFITS OF A CGM?

- ✓ Improved quality of life
- ✓ Reduced risk of hypoglycemia and hyperglycemia
- ✓ Reduced glycemic variability

CURRENTLY AVAILABLE CGMS

Dexcom

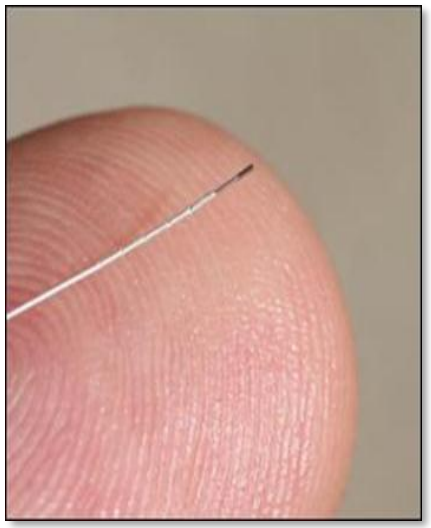
Medtronic

FreeStyle Libre
and Libre 2

Senseonics

Slide courtesy of Daniel Desalvo,MD

DEXCOM G6



Sensor + Algorithm

Factory calibrated
10 Day Session
Acetaminophen blocking

Applicator

Push Button
Sensor
Applicator

Transmitter

BLE - 20 Foot Range
3 Month Life

Apps iOS

Dexcom G6 App
Urgent Low Soon Alert
Remote Monitoring
Clarity

Slide courtesy of Daniel Desalvo, MD

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MEDTRONIC GUARDIAN

670G and 770G Hybrid Closed-Loop system

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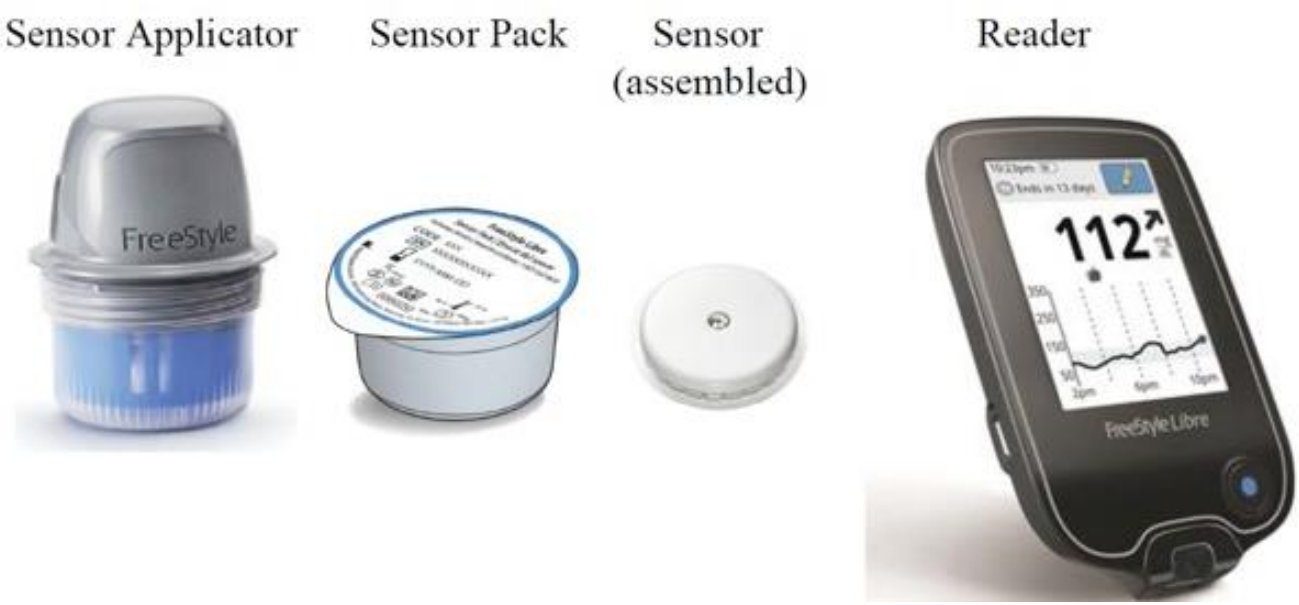
ABBOTT FREESTYLE LIBRE

- Flash Glucose Monitor (FGM)
- Factory Calibrated
- 14-day wear following 12-hr warm-up



Abbott

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SENSEONICS EVERSENSE CGM

Implantable Sensor

1) Pill-sized sensor implanted in upper arm for 3 months
   - 5-8mm incision under local anesthesia
2) Rechargeable transmitter worn on skin above implanted sensor
3) Real-time glucose readings on smartphone app
   - Remote monitoring
4) Provides on-body vibration alerts

Senseonics™

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Slide courtesy of Daniel Desalvo,MD

CURRENTLY AVAILABLE CLOSED LOOP SYSTEMS, AUTOMATED INSULIN DOSING (AID) SYSTEM

Medtronic 670G
and 770G

Tandem T:slim X2
with Control-IQ

TIDEPOOL

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MEDTRONIC 670G AND 770G SYSTEM

- Hybrid closed-loop with basal rate modulation via control algorithm (embedded in pump)
  - Treat-to-target: 120mg/dl, temp target 150mg/dl
  - Adaptive algorithm
- User still boluses for carbs, correction
- Auto mode vs. manual mode
- BG calibration at least 2-4x daily
- 770G – same algorithm and CGM but has Bluetoom Connectivity

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MEDTRONIC 780G – ADVANCED HYBRID CLOSED LOOP

- Autocorrections
- Adjustable target
- Same CGM

- Expected launch: April 2021

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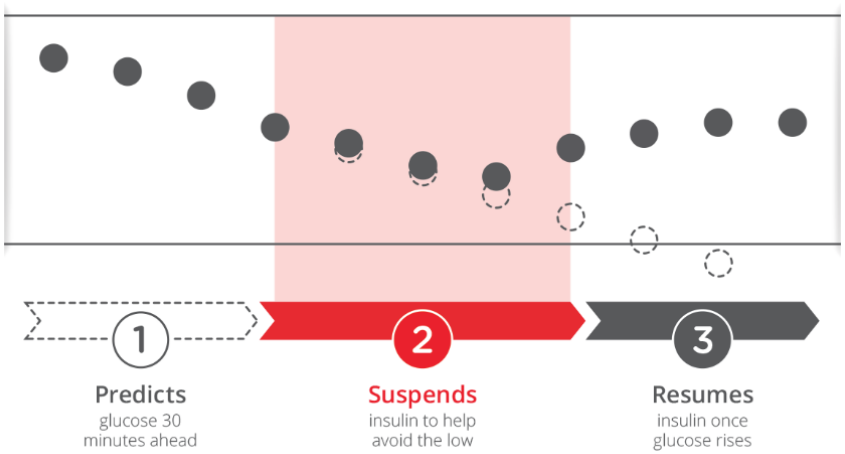
TANDEM DIABETES CARE

Basal-IQ - Predictive Low Glucose Suspend (PLGS)

- t:slim X2 + Dexcom G6
- Free software upgrade (T-Slim updater)
- *Pivotal Study: 30% reduction in hypoglycemia (<70 mg/dl)



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*Forlenza GP et al. *Diabetes Care*, 2018.

Slide courtesy of Daniel Desalvo,MD

TANDEM X2 CONTROL IQ

- Components
  - Tandem T-Slim X2 insulin pump
  - Dexcom G6 sensor
  - Control-IQ = Hybrid Closed Loop (HCL) algorithm
- Rx & training required to upgrade software
- Same hardware as Basal IQ, different software

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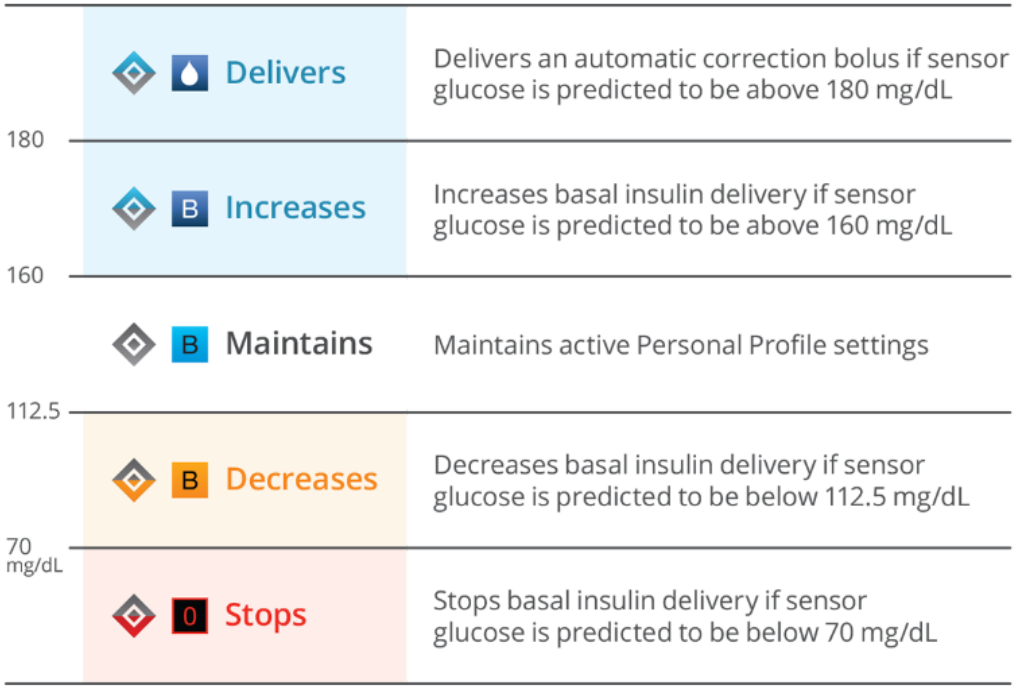
Slide courtesy of Daniel Desalvo,MD

TANDEM X2 CONTROL IQ

The t:slim X2 insulin pump with Control-IQ technology is designed to help increase time in range (70-180 mg/dL)* using Dexcom G6 CGM values to predict glucose levels 30 minutes ahead and adjust insulin delivery accordingly.



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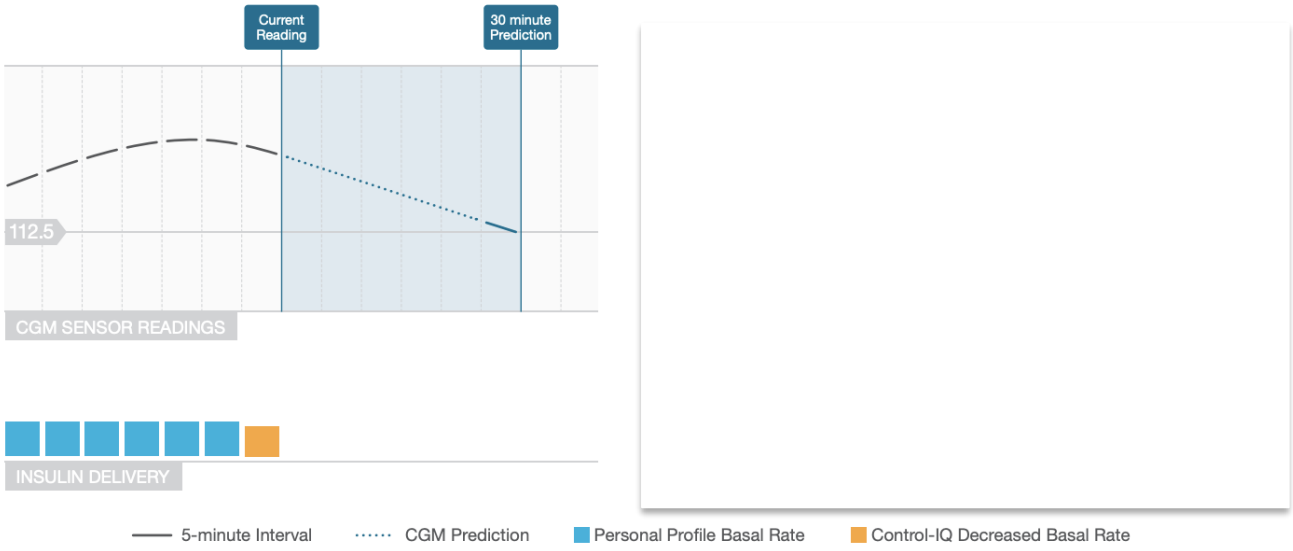
DECREASING BASAL INSULIN



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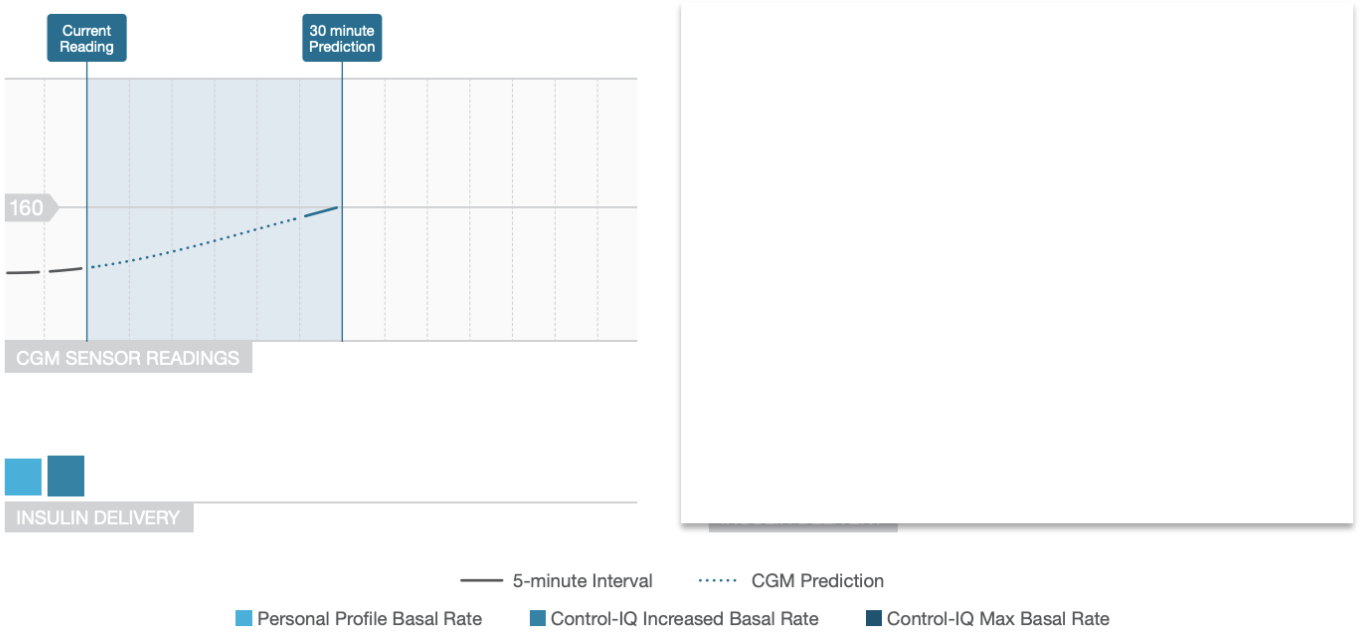
INCREASING BASAL INSULIN



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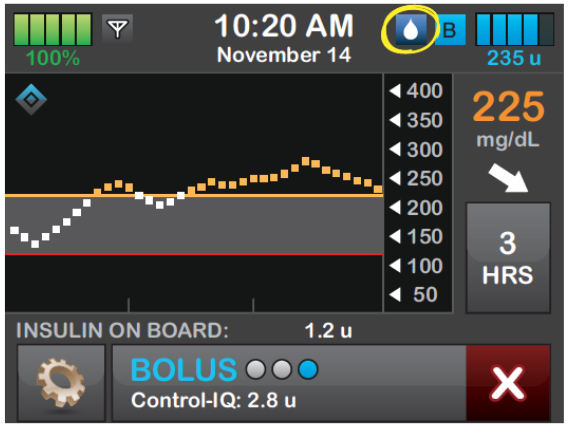
AUTOMATIC CORRECTION BOLUSES

- Up to once per hour if projected glucose >180 mg/dL
- Delivers 60% of calculated correction dose to 110 mg/dL
- Delivers without user confirmation
- Beeps/vibrates like user-initiated boluses
- Factors into insulin on board



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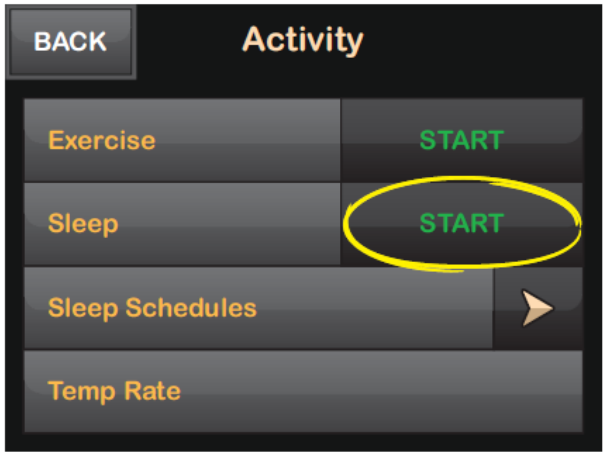
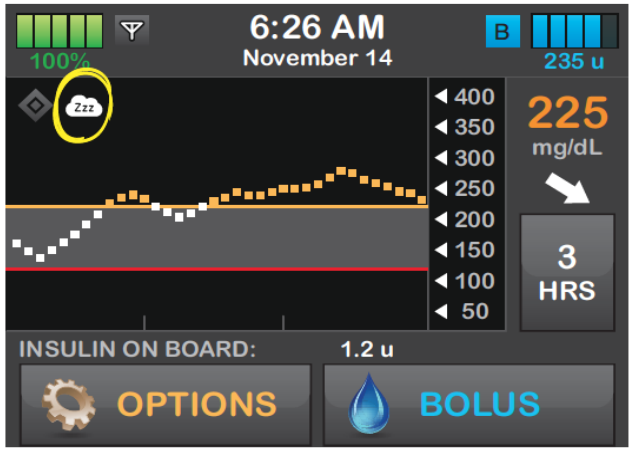
SLEEP MODE

- Narrower target range (112.5 – 120 mg/dL)
- No auto-boluses
- Can set 1-2 schedules (weekday vs. weekends)
- Can start, stop manually





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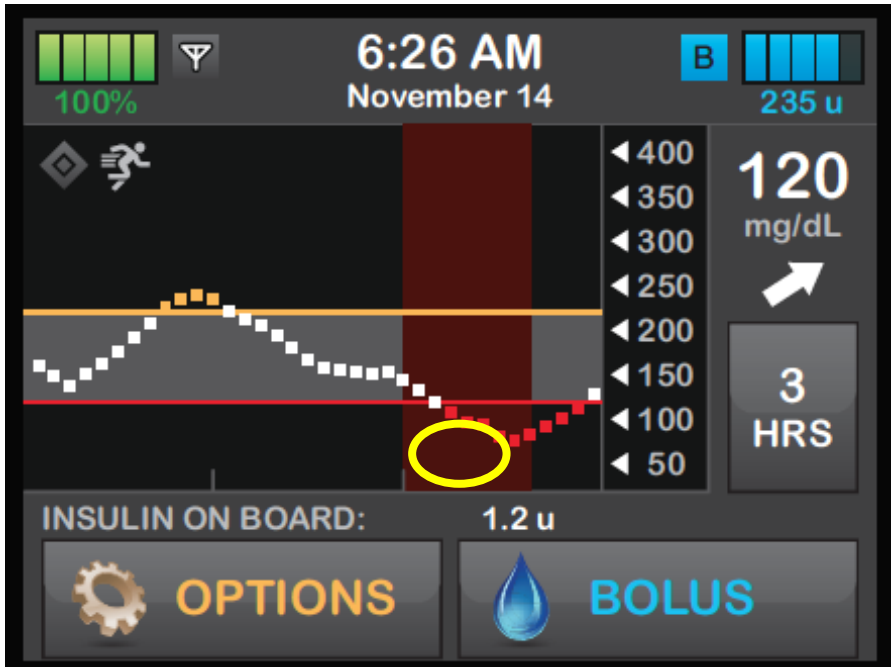
EXERCISE MODE

- "Temporary target range" of 140-160 mg/dL
- Clinical pearls
  - Use like a temp basal
  - Activate 30-60 mins prior to activity
  - Consume carbs if below "*target range*" prior to activity



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Slide courtesy of Daniel Desalvo,MD

WHAT IS TIDEPOOL LOOP?

- It is a DIY automated delivery app for iPhone that connects to an insulin pump and CGM using Bluetooth.
- It runs an algorithm every 5 minutes to adjust the basal rate for the next 30 min.
- Blood glucose targets can be set and can be temporarily changed (i.e. for exercise or before a meal)

TIDEPOOL LOOP

It has an Apple watch app where carbs can be entered, boluses given, temporary basal rates set.

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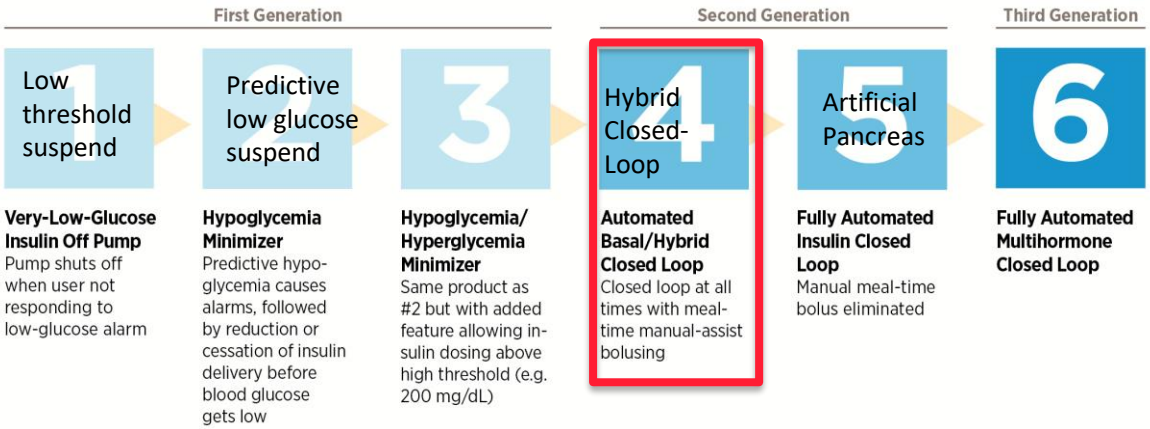
THE QUEST FOR AN ARTIFICIAL PANCREAS



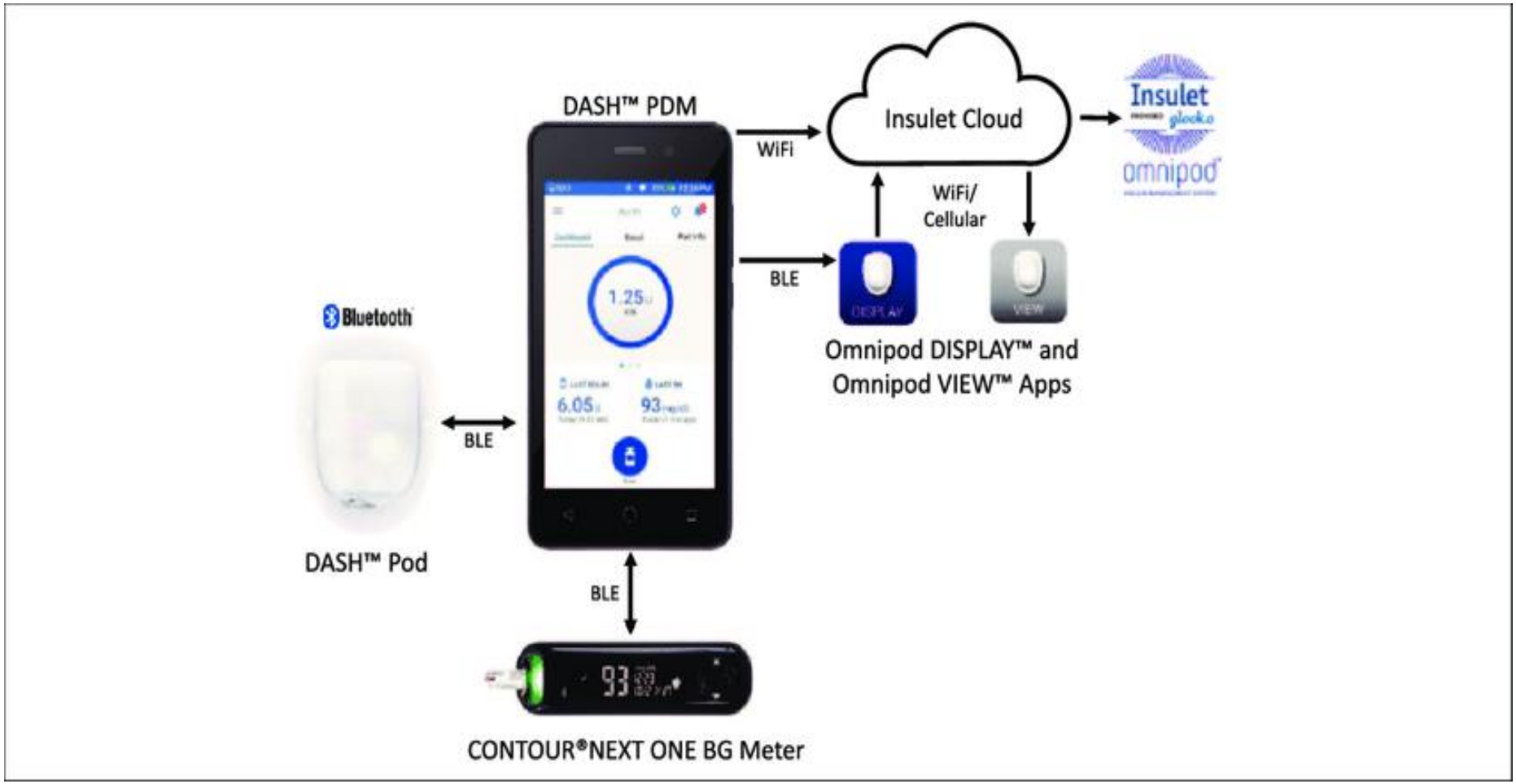
FUTURE DIRECTION

omnipod® HORIZON®
AUTOMATED GLUCOSE CONTROL

Beta Bionics

eversense

OMNIPOD DASH



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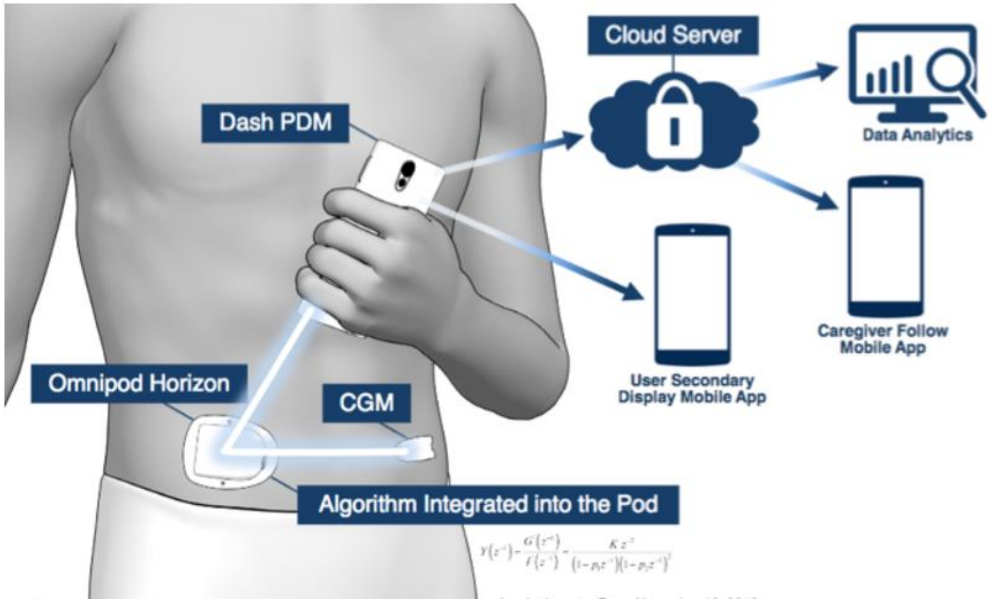
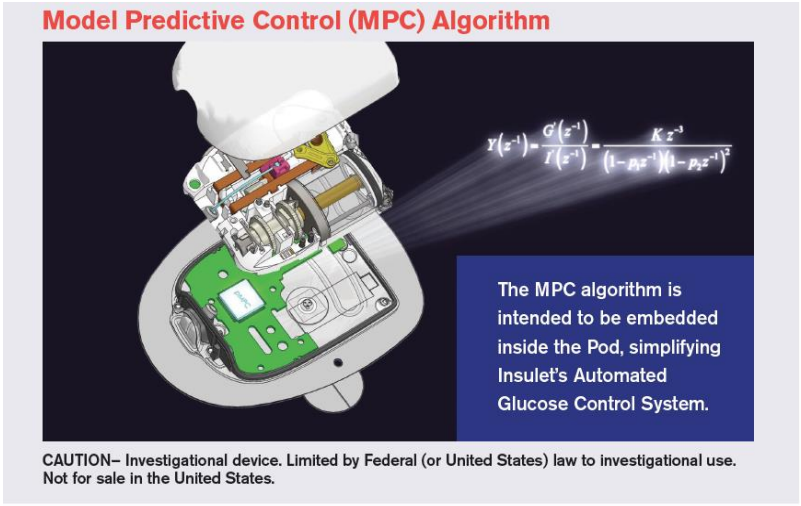
INSULET OMNIPOD HORIZON

Omnipod Horizon: tubeless pod w/ integrated control algorithm

- DASH PDM + Dexcom CGM





1. Ann. N.Y. Acad. Sci. 1311 (2014) 102-123. The Artificial Pancreas: Current Status and Future Prospects in the Management of Diabetes. Thomas Peyser, Eyal Dassau, Marc Breton, Jay S. Skyler.

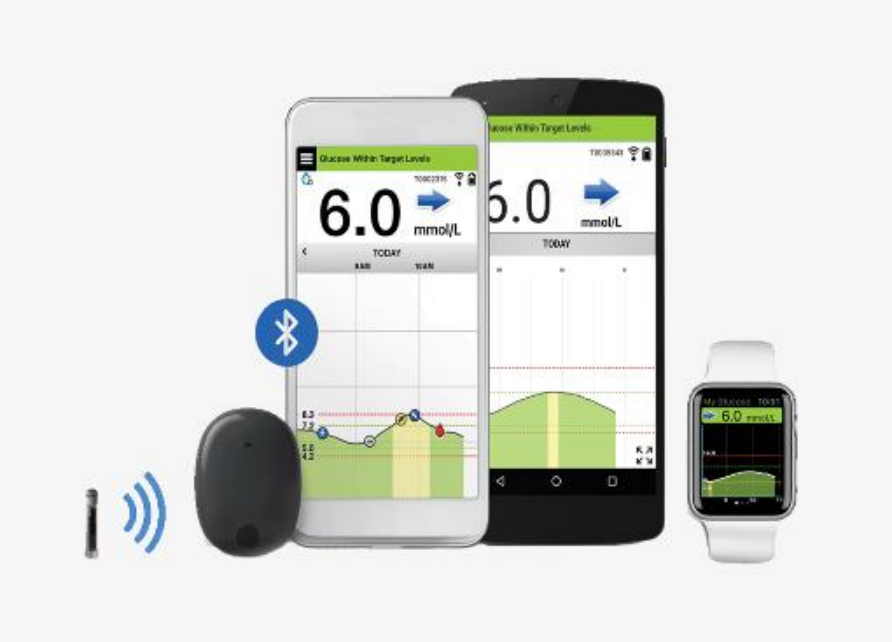
*The Pod has an IPX8 rating for up to 25 feet for 60 minutes. The PDM is not waterproof.

Slide courtesy of Daniel Desalvo, MD

SENSEONICS

Senseonics Eversense XL

- 180 day sensor
- 365 day sensor



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BETA BIONIC ILET

- Enter body weight
- System learns over time
- Bolus based on size of meal (not carb counting)

REFERENCES

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- https://diatribe.org/continuous-glucose-monitors
- https://www.tidepool.org/blog/tidepool-loop-development-update

Thank you!

Questions?

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