

## Institutional Investor & Analyst Day

September 25, 2018









### AGENDA

Welcome.

Company Vision.

Technology Roadmap and Product Innovation.

Financial Outlook and International Expansion.



#### SAFE HARBOR

#### Cautionary Note Regarding Forward-Looking Statements

Certain statements in this presentation constitute forward-looking statements, including, without limitation, statements about: the perceived advantages of our products relative to competitive products and technologies; our anticipated growth and other measures of future operating results and financial performance; the development and commercialization of new products; our ability to secure and maintain necessary regulatory approvals for our existing products and new products under development. Our estimates and forward-looking statements are based on our management's current assumptions and expectations of future events and trends, which affect or may affect our business, strategy, operations or financial performance. These statements are not guarantees of future performance and involve a number of risks and uncertainties, many of which are beyond our control. Our actual results may differ materially from those expressed or implied by such forward-looking statements. Some of the factors that could cause actual results to differ materially from those expressed or implied by such forward-looking statements can be found under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q, as well as in the other reports we file with the Securities and Exchange Commission. In addition, new risk factors and uncertainties emerge from time to time and it is not possible for our management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements. Estimates and forward-looking statements speak only as of the date they were made, and, except to the extent required by law, we undertake no obligation to update or review any estimate and forward-looking statement because of new information, future events or other factors.

#### **Trademarks**

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SLIDE 4







Strong short-term momentum.

Solid long-term growth trajectory.



## **Delivery Device**





## Glycemic Control





# Expanding the market through innovation.

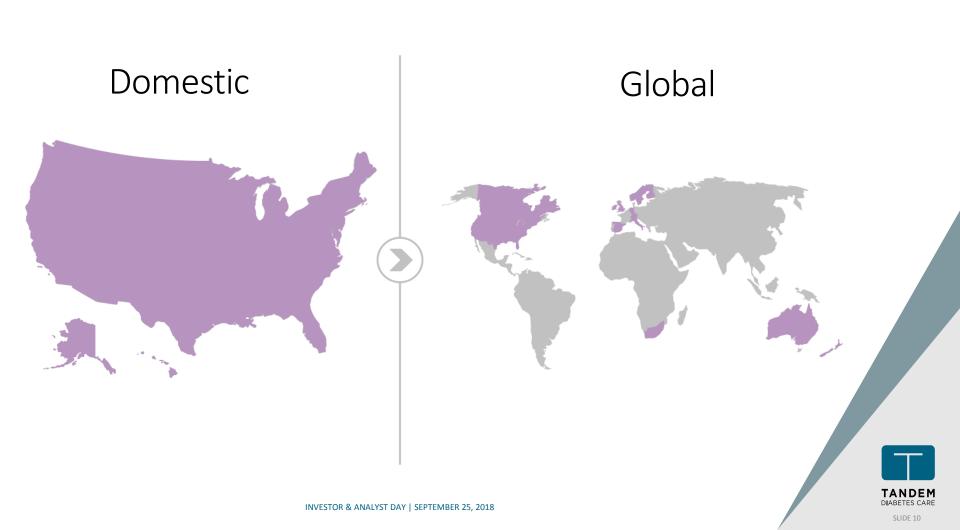












#### **Features**

#### touch simplicity°





Touchscreen



Discrete



Remote Update Capability



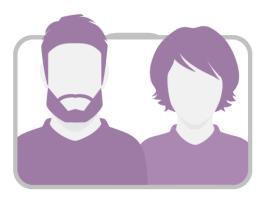
Rechargeable Battery



Dexcom® CGM



#### Clinical Outcomes



Improving time in range and A1c's

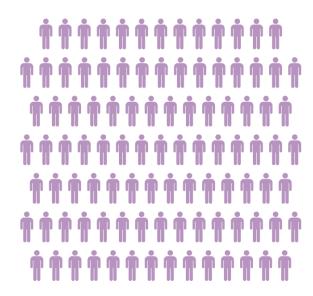
Reducing hypoglycemic events, hospital visits and cost



## \$100 Million Annual Sales



## \$1 Billion Annual Sales

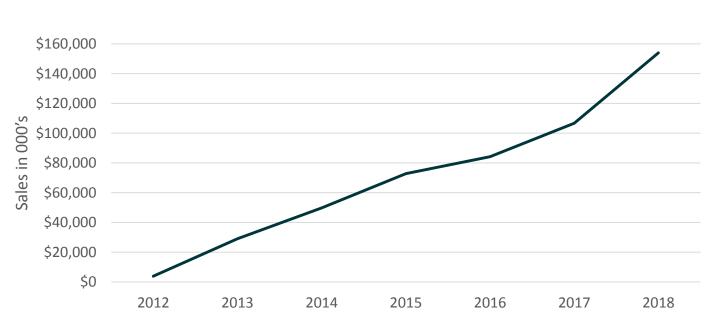




## Domestic Durable Pump Launches & Exits

Manufacturer	2012	2013	2014	2015	2016	2017	2018
TANDEM® DIABETES CARE	t:slim			t:slim G4 & t:flex	t:slim X2	t:slim X2 with G5	t:slim X2 Basal-IQ
Medtronic		530G			630G	670G	
Animas® a gohnson gohnson company				Vibe G4		Exit	
Roche	Spirit Combo					Exit	
asante.		Snap		Exit			

## Tandem's Growth.



Updated 2018 Sales Guidance: \$150M - \$158M



Cadence of annual new product launches.

Growing the worldwide insulin pump market and capturing share.

Increasing leverage. Reducing losses.

Debt free.









Tandem Diabetes Care® is dedicated to improving the lives of people with diabetes through relentless innovation and revolutionary customer experience.



Tandem Diabetes Care® is dedicated to improving the lives of people with diabetes through relentless innovation and revolutionary customer experience.





First.

Fast.

Smart.

Customer Focused.







Touch screen.

Rechargeable battery.

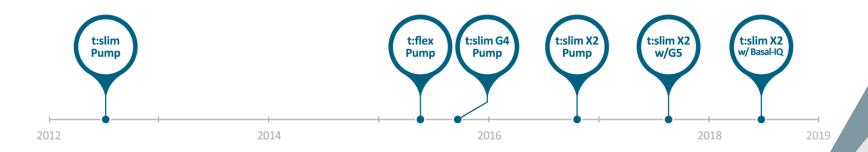
Remote updateable software.

Designation as compatible with iCGM.

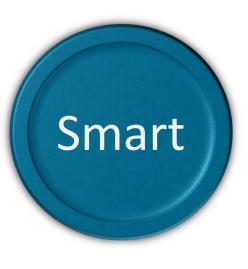
Part of an automated insulin delivery system requiring no finger sticks.











Reliability & manufacturing efficiencies.

Internal development processes.

Automation.

Partnerships.

Lean R&D investment.





Easy to use.

Look and feel like a consumer device.

Software updatable.

#1 rated customer service.





Regulatory strategy.

Automated insulin delivery.

Connected health.



Interoperability is changing the regulatory landscape.



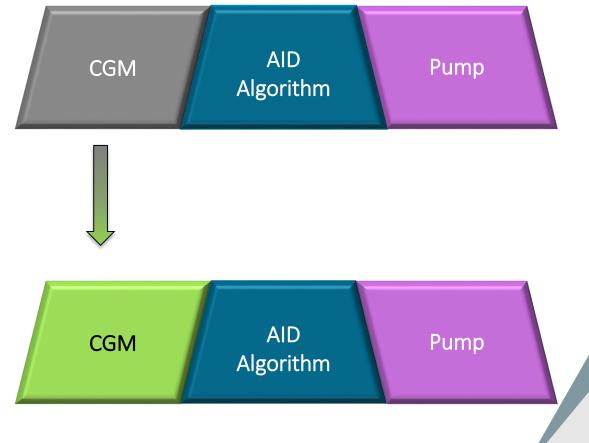
Historical PMA system approval.

required new PMA,

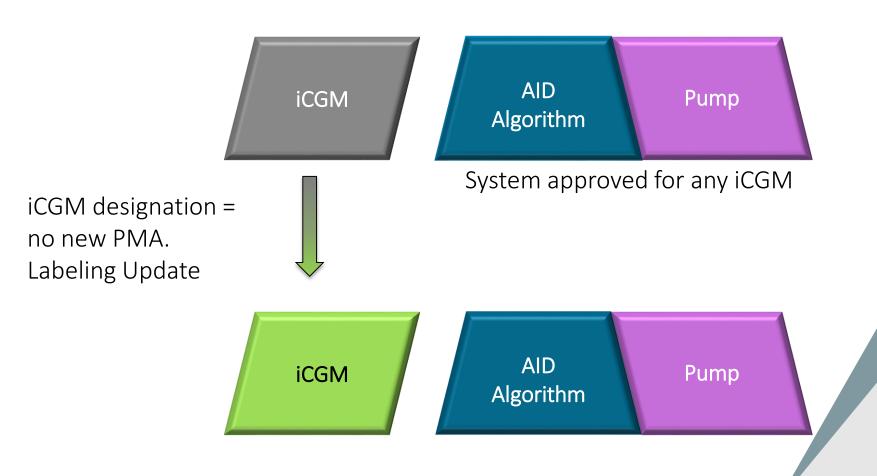
New system approved.

CGM change

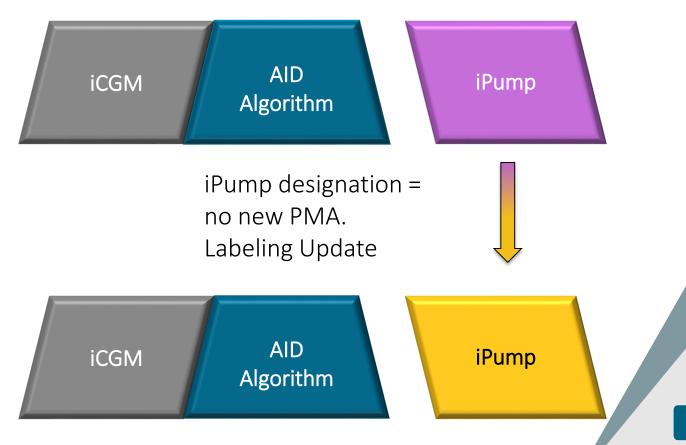
new clinical data.

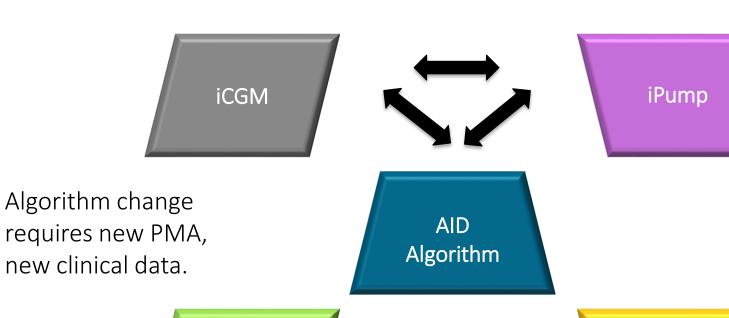


**TANDEM** 













iPump



Interoperable systems can include devices from multiple companies.

Business agreements define product development, product support & financial terms.



# Updated Regulatory Strategy



Previously planned to file a modular PMA in September.

Now submitting an application for an interoperable pump as part of an AID System (iPump).

Followed by a PMA submission for the AID algorithm.

No change to launch goal of Summer 2019.

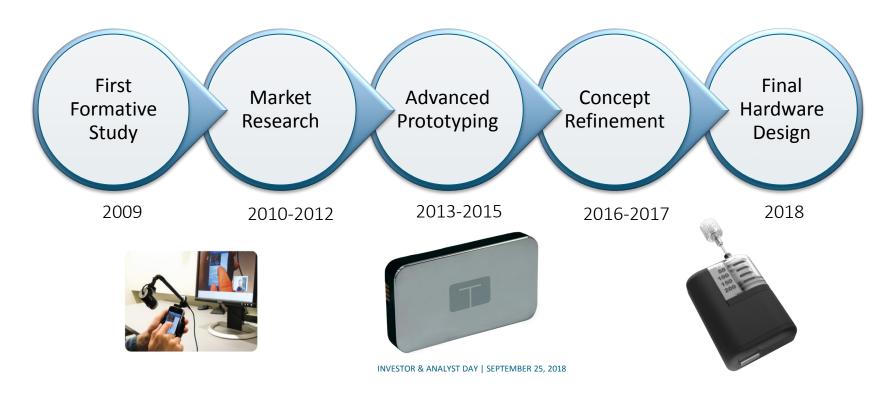
t:slim X2 with Control-IQ Technology



Escalating t:sport development.



## The Evolution of t:sport



## Love Your Tubing.



Freedom to disconnect.

Reduce insulin waste if and when adhesives fail.

Preserves current reimbursement model.



Small Pump with Tubing

Quick & Easy Fill Process

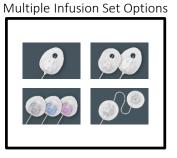


Syringe Delivery



AID Algorithm

Hybrid Closed Loop Algorithm



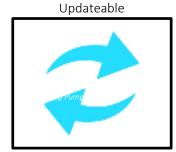
iCGM Integration



Bluetooth® Radio



Wireless Charging





Predicted Trend



INVESTOR & ANALYST DAY | SEPTEMBER 25, 2018



Ability to Disconnect from Site



Water Resistant (IPX8)





Controlled using a mobile app or a separate touchscreen controller.

FDA submission as an iPump enabling use of Control IQ with no new clinical data.

Launch goal: 2H 2020.



Automated Insulin Delivery



# Predictive Low Glucose Suspension: What, Why, How, and Who? **SUSPENSION**

LAUREL H. MESSER, RN, MPH, CDE

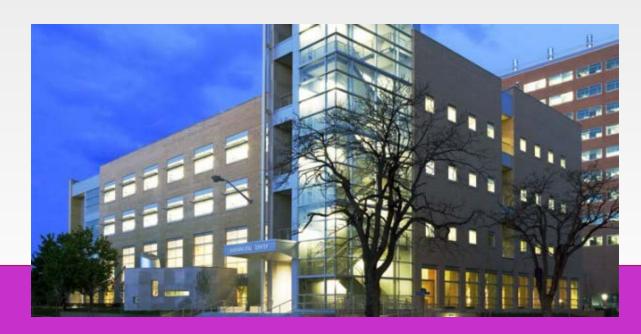
SENIOR INSTRUCTOR, BARBARA DAVIS CENTER, UNIVERSITY OF **COLORADO** 



**PERIOD** 

#### Disclosures for Laurel Messer

- Contract Certified Product Trainer for Medtronic
- Received speaking honoraria from Tandem Diabetes Care
- Consultant: Tandem Diabetes, Capillary Biomedical, Clinical Sensors





# Predicted Low Glucose Suspend: What, Why, How and Who?

- What is PLGS? Why do we need it?
- How does it work?
- PROLOG study results
- Patient experience



## Why suspend insulin?

- HYPOGLYCEMIA— glucose levels dangerously low
- SEVERE HYPOGLYCEMIA: United States registry data:
  - o 11.8% adults experienced severe hypo in past 12 months<sup>1</sup>
  - o 6% Loss of consciousness or seizure in past 3 months<sup>2</sup>
  - O Higher risk:
    - Higher age<sup>2</sup>
    - Longer diabetes duration<sup>1,2</sup>
    - Insulin injections v insulin pump<sup>2</sup>
    - Lower education level and household income<sup>1</sup>



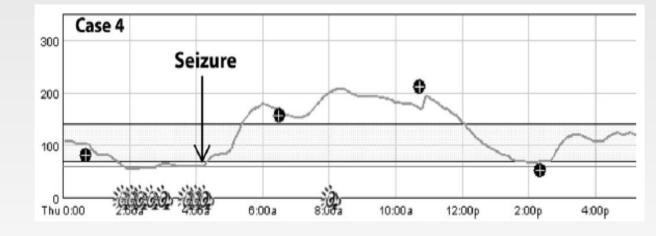
#### Nocturnal Hypoglycemia

- The overnight period is a particularly dangerous time for hypoglycemia.
- Sleep impairs hypoglycemia counter-regulation.
- •Many individuals with T1D have impaired awareness of hypoglycemia.

#### Duration of Nocturnal Hypoglycemia Before Seizures

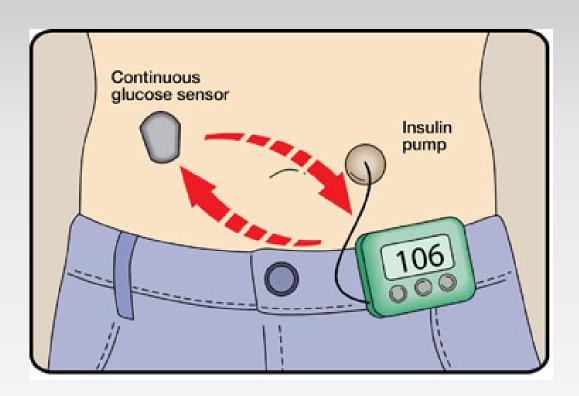
BRUCE BUCKINGHAM, MD<sup>1</sup> DARRELL M. WILSON, MD<sup>1</sup> TODD LECHER, MPH<sup>2</sup> RAGNAR HANAS, MD, PHD<sup>3</sup> KEVIN KAISERMAN, MD<sup>4</sup> FERGUS CAMERON, MD<sup>5</sup>

DIABETES CARE, VOLUME 31, NUMBER 11, NOVEMBER 2008





#### Hypoglycemia: How to prevent?



- Automated insulin systems
- Insulin delivery that is responsive to glucose levels

Glucose sensor



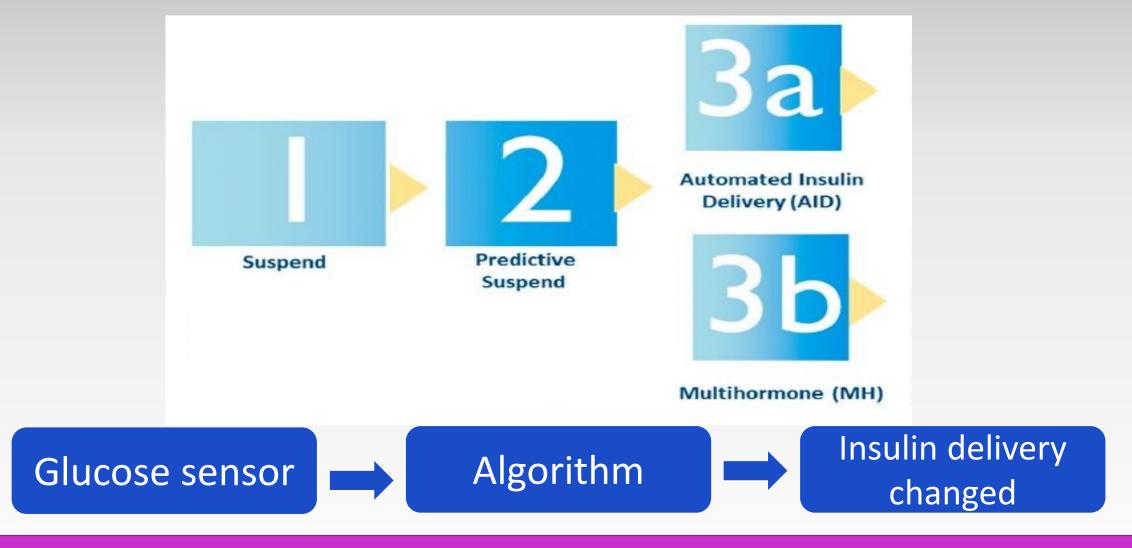
Algorithm



Insulin delivery changed

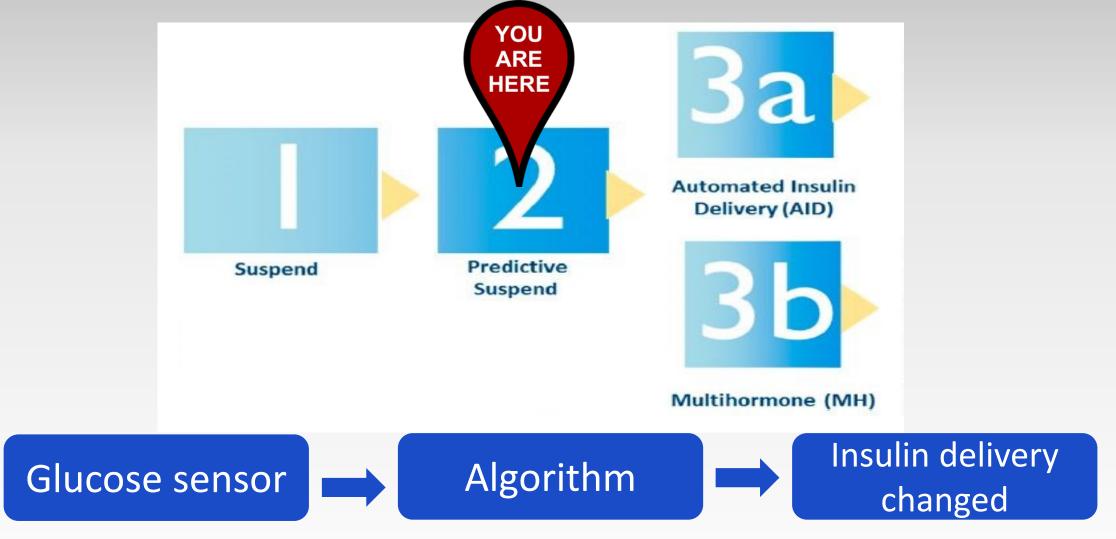


# **Automated Insulin pathway**



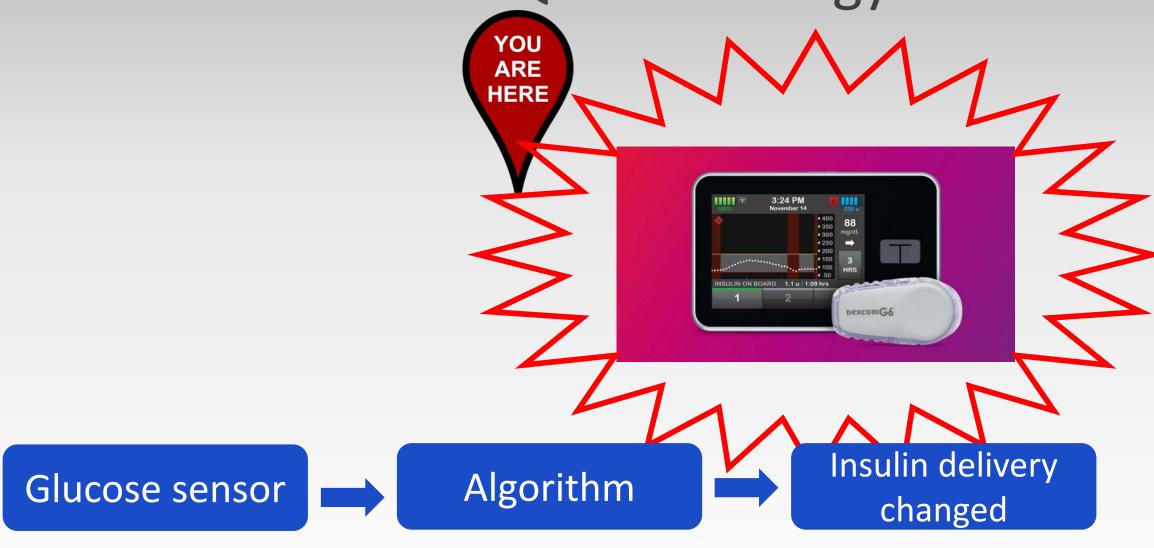


# **Automated Insulin pathway**





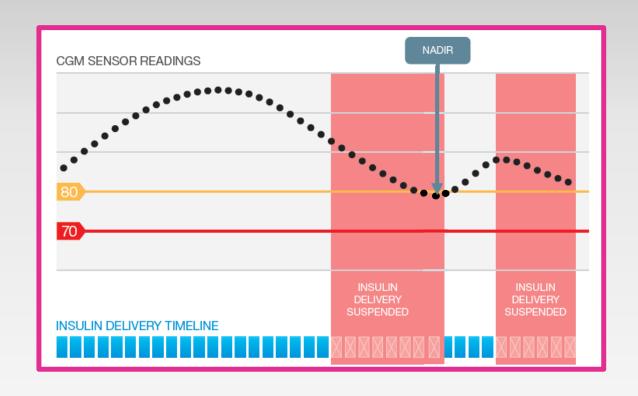
#### t:slim X2™ with Basal-IQ™ Technology





# Predictive Low Glucose Suspend (PLGS)

- Sensor glucose levels falling...
- Algorithm predicts hypoglycemia in future
- 3) Insulin pump stops delivering insulin



Glucose sensor



Algorithm



Insulin delivery changed



**Figure 1**. PLGS Example Patient (TAND1-001-0001): CGM and Reference Glucose Values (top) and Insulin Infusion Rates (bottom) 300 -CGM YSI 250 × MBG Glucose (mg/dl) or g CHO \* Suspend 200 Resume Carbs 150 △ Ins Challenge 100 70 Suspension tribeered 50 Insulin resumed Multiple shurors 0 21:00 02:00 05:00 11:00 18:00 19:00 20:00 00:90 07:00 08:00 00:60 10:00 12:00 **Basal Rate** sal Rate Bolus Insulin infusion rate (U/hr) 3 Insulin (U) 2

1

0

18:00

19:00

20:00

21:00

22:00

23:00

00:00

01:00

02:00

03:00

04:00

05:00

00:90

07:00

08:00

00:60

10:00

11:00

12:00

3

# Predicted Low Glucose Suspend: What, Why, How and Who?

- What is PLGS? Why do we need it?
- How does it work?
- PROLOG study results
- Patient experience



# PROLOG: PLGS for Reduction of Low Glucose

- Pivotal trial for PLGS
- Design: 6-week crossover RCT (3 weeks control, 3 weeks PLGS)
  - Control Arm: t:slim X2™ pump with commercially approved features and a Dexcom G5® CGM.
  - Experimental Arm: t:slim X2 pump with Basal-IQ™ PLGS feature.
- •Multi Center study in pediatrics and adults.
- ■103 subjects ages 6-72 years old



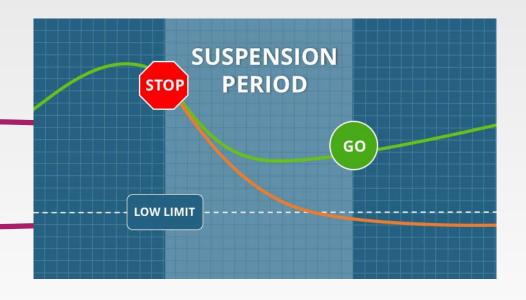
#### **Summary of PROLOG study**

- Significant reduction in hypoglycemia with PLGS (all metrics)
- 31% relative reduction in mean time <70 mg/dl</p>
- Greater effect in participants with greater baseline hypoglycemia
- Safety
  - No safety issues
  - No increase in mean glucose or hyperglycemia
- System suspensions of insulin delivery on almost all days with median cumulative suspension time per day of 90 minutes
- Participant satisfaction with the system extremely high



# Predicted Low Glucose Suspend: What, Why, How and Who?

- What is PLGS? Why do we need it?
- How does it work?
- PROLOG study results
- Patient experience



## t:slim X2<sup>TM</sup> with Basal-IQ<sup>TM</sup>

- No fingersticks: Dexcom G6® glucose sensor
  - No fingersticks for calibration
  - No fingersticks needed for insulin dosing
- •Minimal alerts
  - Prevents hypoglycemia without disruption





# Basal-IQ<sup>TM:</sup> What should patients expect?

#### Better quality of life

- Less worry about hypoglycemia, especially in overnight period
- Requires little to no BG tests (no calibration and approved to dose insulin based on SG value)





#### Summary

- Hypoglycemia is a common problem for people with T1D
- Basal-IQ (PLGS) can reduce occurrences of hypoglycemia (31% in PROLOG study)
- •High user satisfaction— no fingersticks, minimal alarms, easy to use
- PLGS is important step in Automated Insulin Delivery pathway



#### **Automated Insulin**

Automated Insulin is the future of insulin pumps and CGMs



Glucose sensor



Algorithm



Insulin delivery changed



## Thank you!

Laurel.Messer@ucdenver.edu



SCHOOL OF MEDICINE

Barbara Davis Center for Diabetes

JNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS



# Our Path to Automated Insulin Delivery

Patrick Keith-Hynes, PhD
Chief Science Officer
TypeZero Technologies Inc

Tandem Diabetes Care September 25, 2018

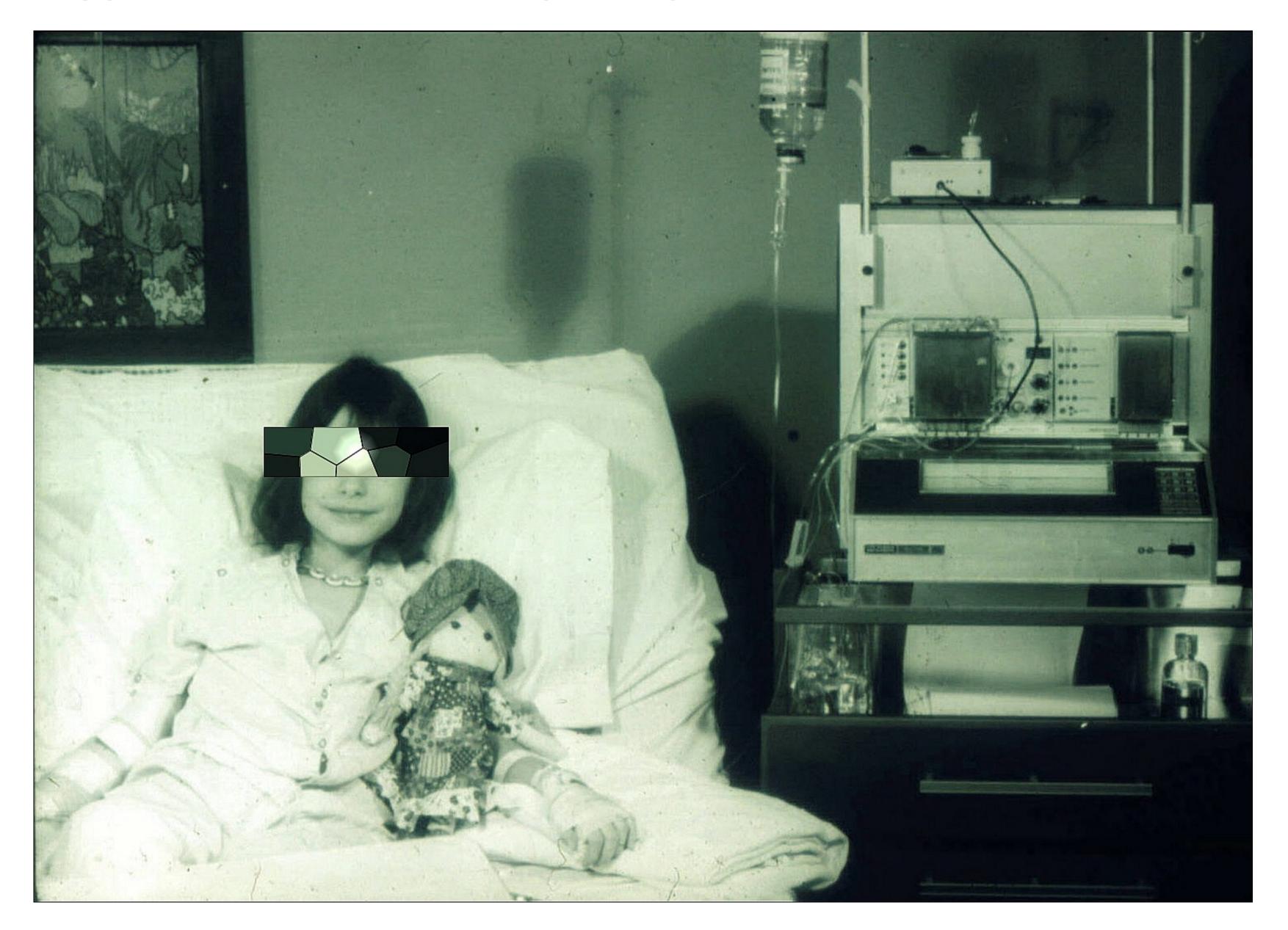


# flypezero

- Brief History of TypeZero Algorithm
- inControl System
- Studies and Results

#### AUTOMATED INSULIN DELIVERY - THE BEGINNING



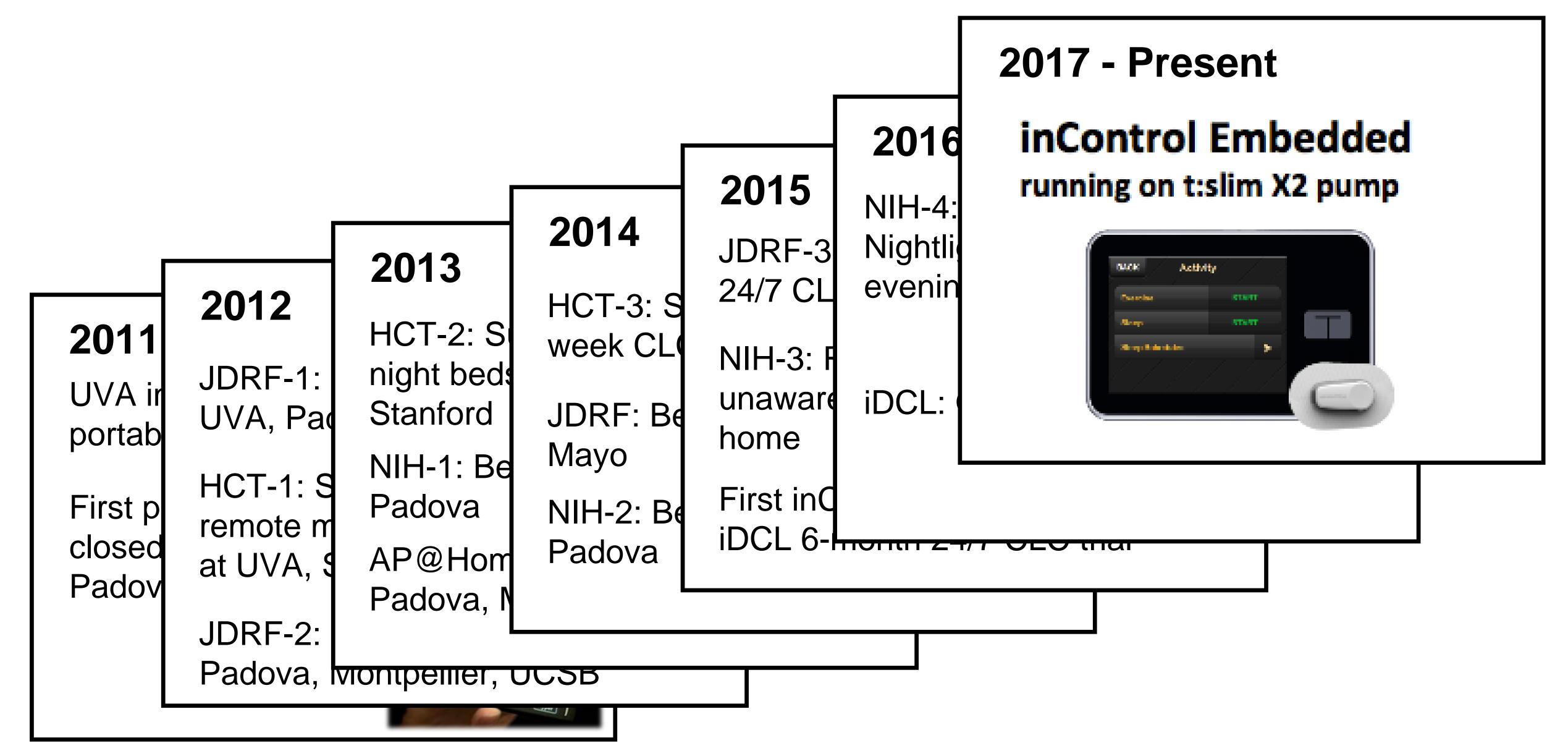


#### BACKGROUND

- Core technology is based on 10+ years of R&D
- . All developed with Dexcom CGM
- . NIH, JDRF, UVA, Helmsley have invested more than \$40 million to date
- . 30 clinical studies
- . 450 patients
- > 300,000 hours of use in human trials







# inControl Overview

- . Robust, exhaustively tested modular algorithmic stack
- . Improved glycemic time in range with dramatically reduced hypoglycemia
- Highly differentiated User Experience with best of class CGM



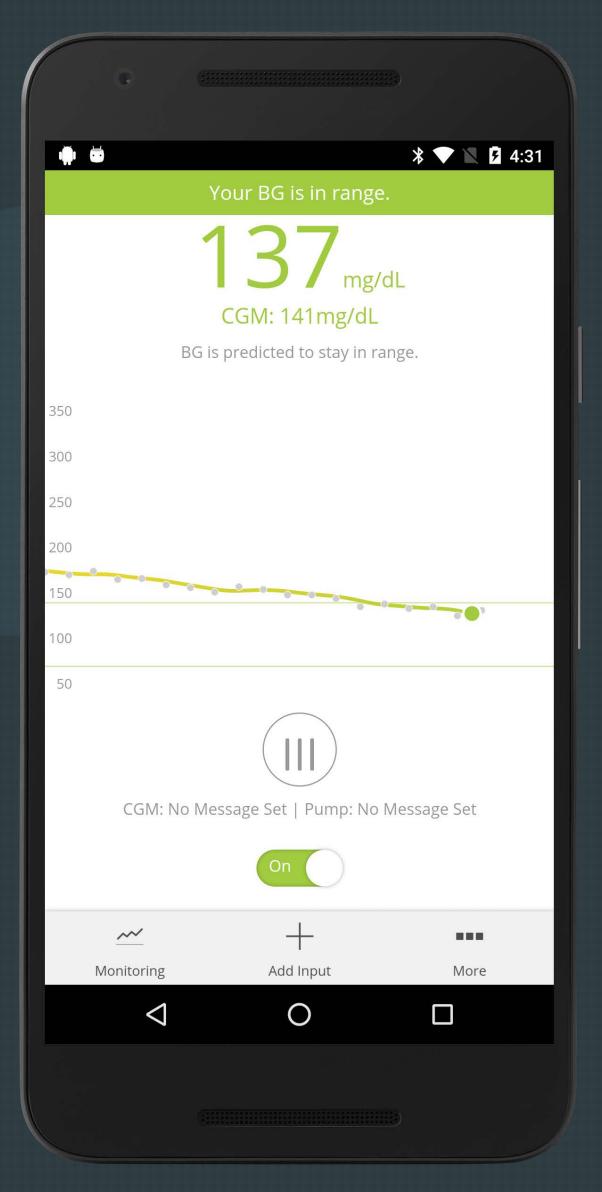
# inControl Features

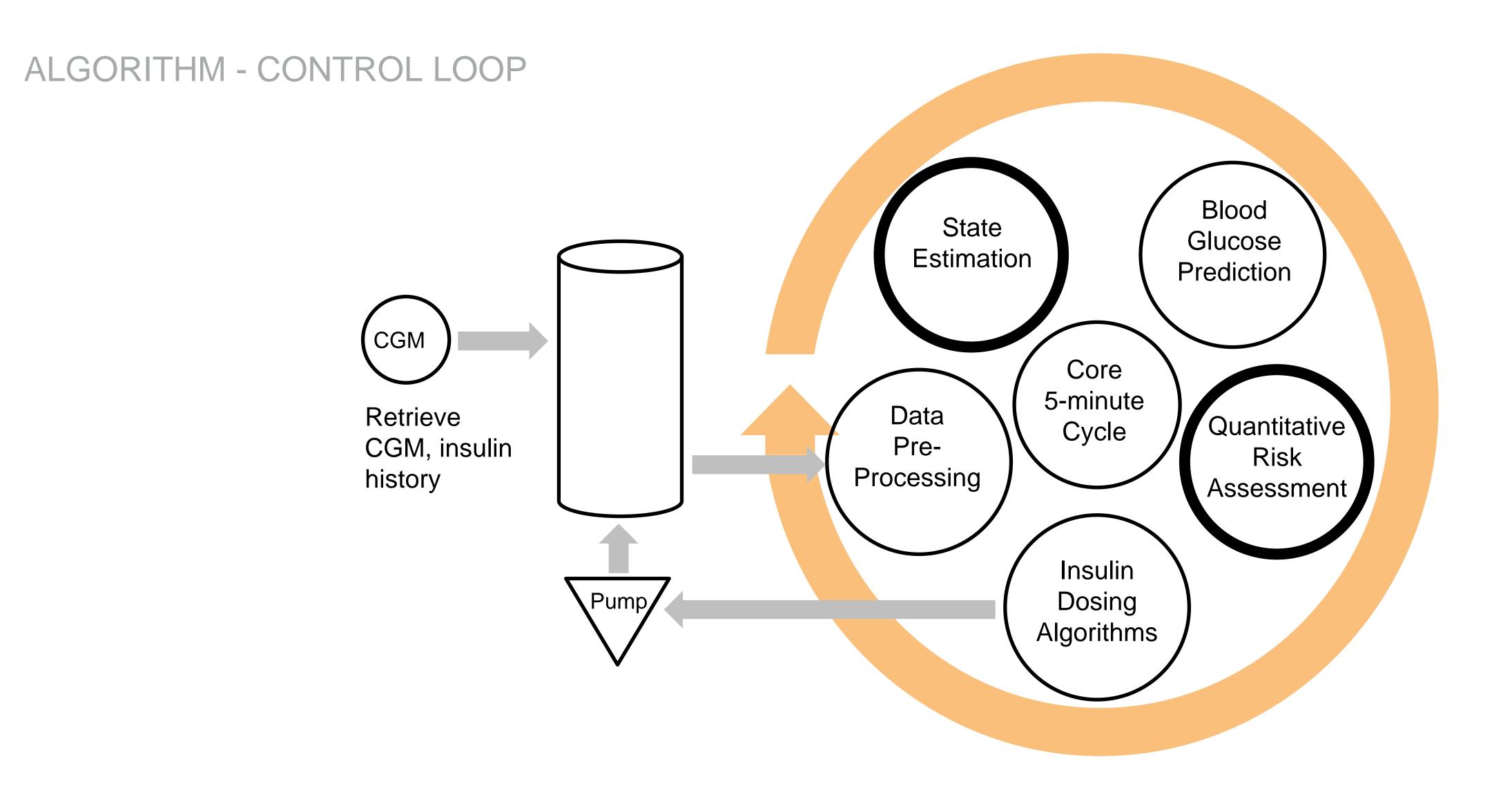
- Modular Closed Loop Control increases glycemic time in range while dramatically reducing hypoglycemia
- . System automatically <u>and smoothly</u> decreases insulin infusion rate based on predicted hypoglycemic risk
- Automatically modulates basal infusion and generates <u>correction boluses</u> in response to predicted hyperglycemia





- Metabolic State Estimation
- Quantitative Risk Assessment





Measure > Model > Predict > Act > Repeat



Basal Attenuation Module smoothly reduces basal insulin delivery in response to predicted hypoglycemia

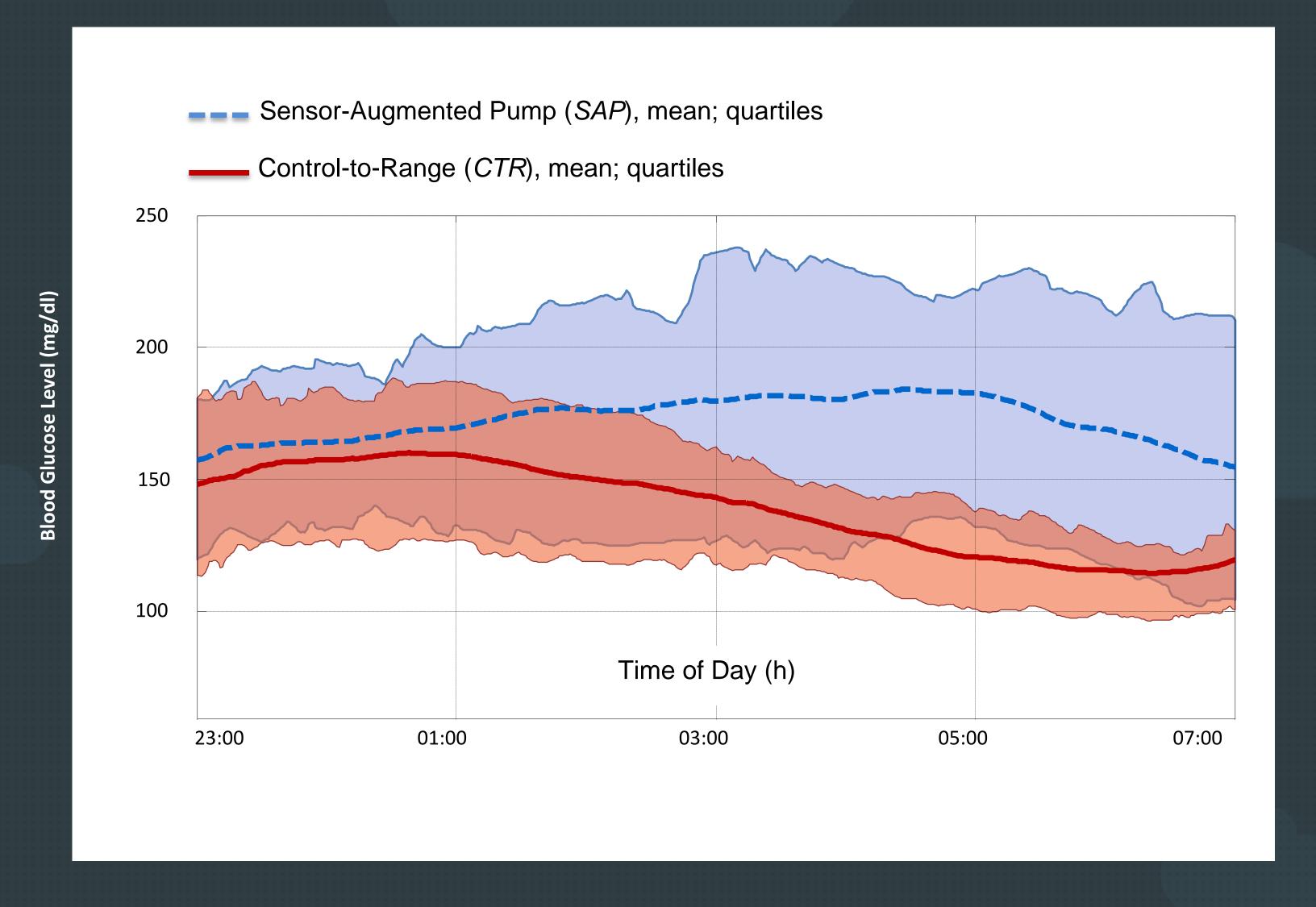
Hypo Safety

Basal Increase Module manages increased basal rate in response to hyperglycemia prediction

Hyperglycemia Correction Module delivers periodic automated correction boluses as needed



#### RESULTS FROM OVERNIGHT INTENSIVE INSULIN THERAPY



Brown, Kovatchev et al, Diabetes Technology and Therapeutics, 2015

#### ALGORITHM PERFORMANCE - STANFORD SUMMER CAMP



Publication	Ly, Buckingham et al, Diabetes Care, 2016
Structure	24/7 - 17 subjects, 85 days and nights
24/7 Time 70-180 mg/dl	78.6%
24/7 Time below 70 mg/dl	1.8%

#### ALGORITHM PERFORMANCE - 6 MONTH HOME USE



Publication	Kovatchev, Cheng et al, Diabetes Technology and Therapeutics, Vol 19 Number 1 2017
Structure	24/7 - 14 subjects, 6 months at home
24/7 Time 70-180 mg/dl	77%
24/7 Time below 70 mg/dl	1.3%

#### IDCL TRIAL - NIH UC4 DK 108483 (2016-19)

#### Primary Outcome:

• Time < 70 mg/dl with non-inferiority for time above 180 mg/dl

#### **Secondary Outcomes:**

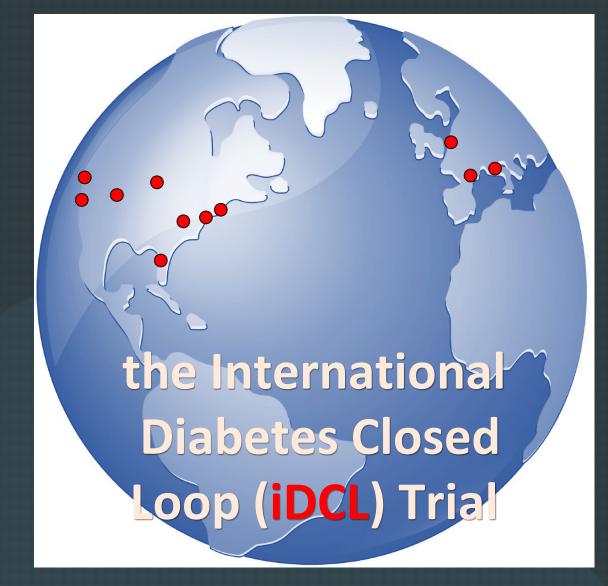
• hba1c, technology acceptance

#### Objectives:

- Establish Closed Loop Control as a viable treatment for T1DM
- Generate safety and efficacy data useable by regulatory bodies
- Demonstrate clinical effectiveness to facilitate reimbursement

#### Design:

 N=249 participants in 6-month RCT comparing Closed-Loop with SAP



University of Virginia
Harvard University
Mount Sinai School of Medicine
Mayo Clinic
Barbara Davis Diabetes Center
Stanford University
William Sansum Diabetes Center
Academic Medical Center Amsterdam
University of Montpelier
University of Padova
Coordinated by JAEB Center



#### KEY TAKEAWAYS

- . TypeZero algorithm is robust and exhaustively tested
- . Improved glycemic time in range with dramatically reduced hypoglycemia
- Highly differentiated User Experience with best of class Dexcom CGM



# flypezero

THANK YOU

# Control-IQ Technology: Automated Insulin for Better Glycemic control

LAUREL H. MESSER, RN, MPH, CDE

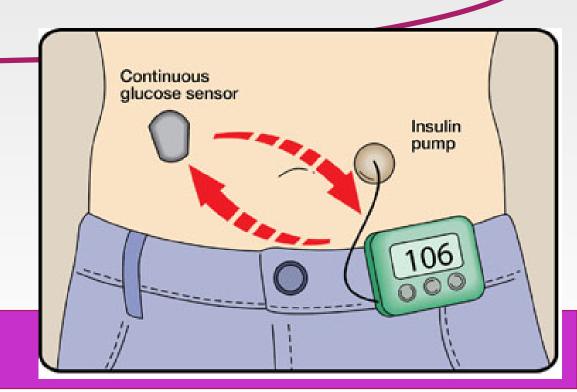
SENIOR INSTRUCTOR,

BARBARA DAVIS CENTER, UNIVERSITY OF COLORADO



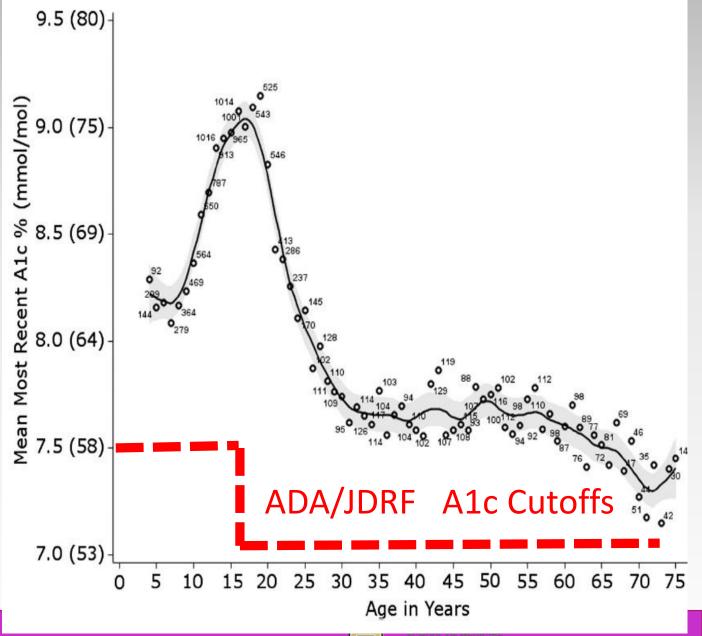
# Control IQ: Automated insulin for better glycemic control

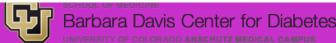
- Why do we need Control-IQ?
- How does it work?
- Ongoing studies
- Patient experience



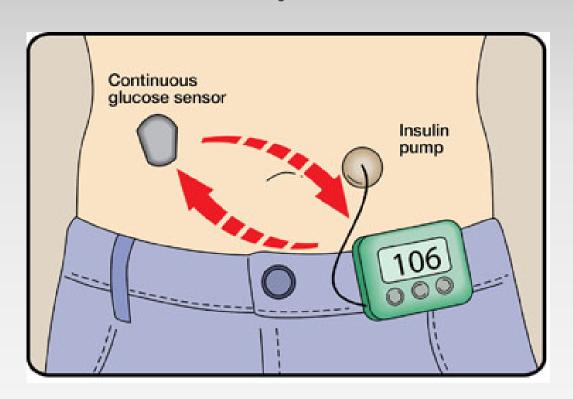
## Glycemic control

- Hypoglycemia
- Hyperglycemia
- 2015 data on overall glycemic control in United States





#### How to improve overall glucose control?



- Automated insulin systems
- Insulin delivery that is responsive to glucose levels

Glucose sensor



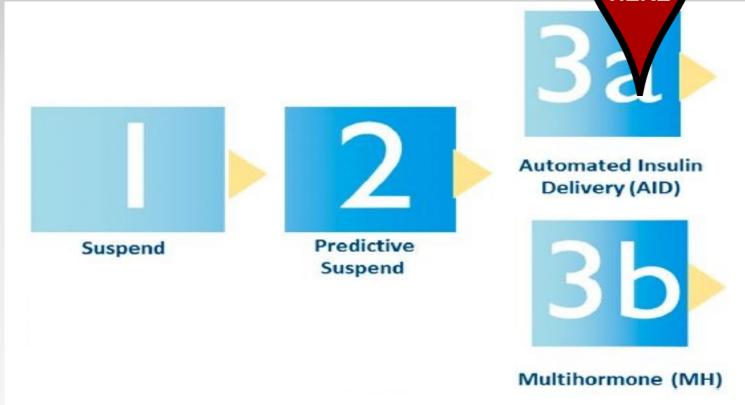
Algorithm



Insulin delivery changed



# Automated Insulin pur way



Glucose sensor



Algorithm



Insulin delivery changed



## Control-IQ: Automated Insulin delivery

Glucose sensor



Algorithm



Insulin delivery changed

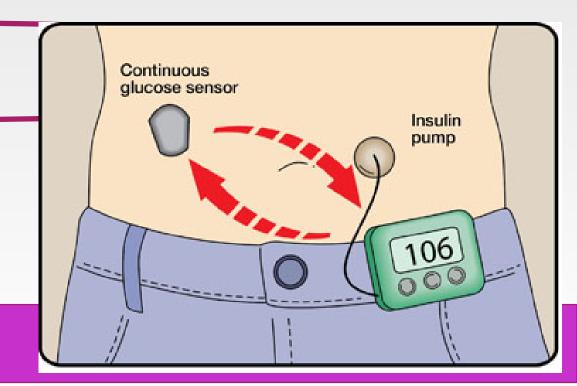
- ■OK glucose → Programmed insulin
- ■Low glucose → Less insulin
- ■High glucose → More insulin

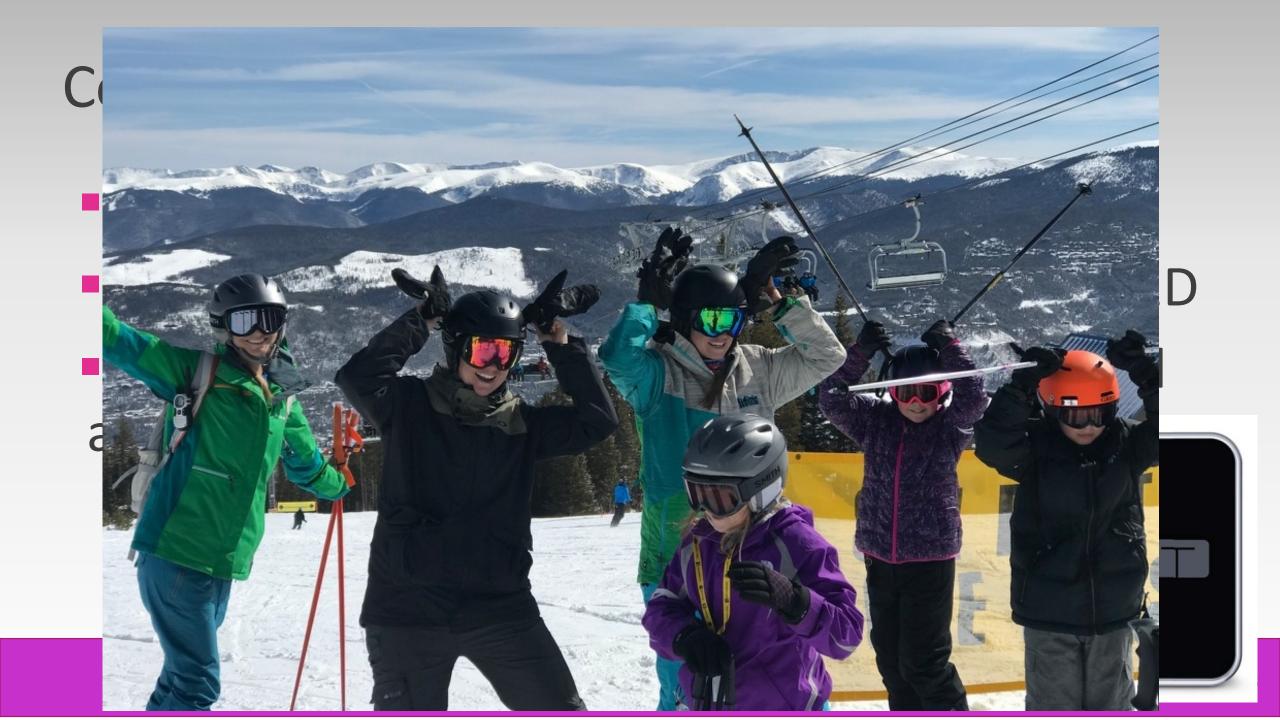




# Control IQ: Automated insulin for better glycemic control

- Why do we need Control-IQ?
- How does it work?
- Ongoing studies
- Patient experience





## 2018: Control-IQ ski camp

- 3 days/2 nights in Breckenridge, Colorado
- 12 children ages 6-12 with T1D
- Randomized: ½ control group, ½ Control-IQ group
- Went home for three days wearing system



## Results of Ski Camp

- Everyone had fun!
- No one broke any bones!
- System performed very well...
- But that's all I can say



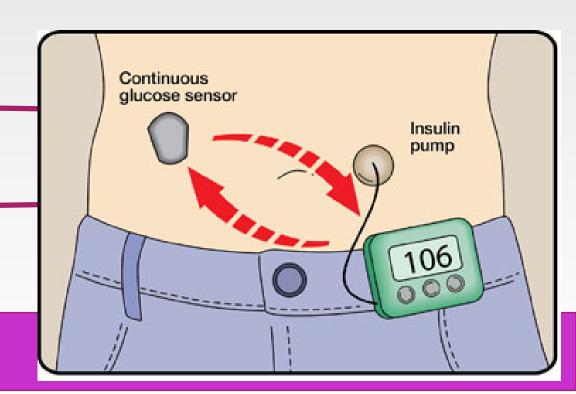
#### Current Control-IQ pivotal trial

- Clinical Trials NCT03563313
- 6 month RCT comparing Control-IQ with standard insulin pump and sensor
- Ages 14-75 years old
- 168 participants
- Outcome: Time in glucose range 70-180 mg/dl

ms and Interventions	Go to ▼
Arm 😉	Intervention/treatment ①
Experimental: Closed Loop Control (CLC)  Participants randomized to the closed loop control (CLC) arm will use the t:slim X2 with Control-IQ Technology & Dexcom G6 CGM for 6 months.	Device: t:slim X2 with Control-IQ Technology & Dexcom G6 CGM Participants will use the Tandem t:slim X2 with Control-IQ Technology & Dexcom G6 CGM for 6 months at home.
Active Comparator: Sensor- Augmented Pump (SAP)  Participants randomized to sensor-augmented pump (SAP) will use an insulin pump with no automated insulin delivery and a study CGM (Dexcom G6) for 6 months.	Device: Sensor-augmented pump (SAP)  Participants will use an insulin pump with no automated insulin delivery and a study CGM (Dexcom G6) for 6 months at home. Pump-users at the time of enrollment will use their personal pump in this arm. Multiple daily injection (MDI) users at the time of enrollment will use a t:slim X2 insulin pump without Control-IQ technology.

# Control-IQ Technology: Automated insulin for better glycemic control

- Why do we need Control-IQ?
- How does it work?
- Ongoing studies
- Patient experience



#### t:slim X2<sup>TM</sup> with Control-IQ<sup>TM</sup>

- Technology acceptance comes down to:
  - Usefulness
  - Ease of Use

Ease of Use

Technology acceptance

Usefulness

# t:slim X2<sup>TM</sup> with Basal-IQ<sup>TM</sup>

- HIGH EASE OF USE
- No fingersticks: Dexcom G6® glucose sensor
  - No fingersticks for calibration
  - No fingersticks needed for insulin dosing
- Minimal alerts
  - Prevents hypoglycemia without disruption
- Remote software updating (new versions, new functionality, etc.)



## t:slim X2<sup>TM</sup> with Control-IQ<sup>TM</sup>

- HIGH USEFULNESS
- Assistance mitigating HIGH and LOW glucose levels
- Expect more glucose levels in target range





## What are our study patients saying?

- Sleeping through the night for the first time since diagnosis
- Not having to interrupt life to test glucose levels and treat low/high glucose levels
- Feeling safer driving, working, etc.
- Better glucose control with exercise

## Thank you!

Laurel.Messer@ucdenver.edu



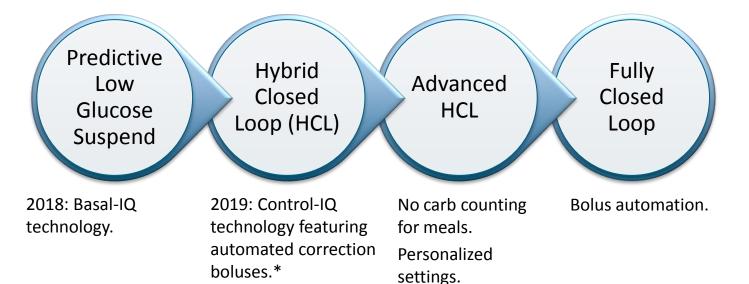
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Xavier de Anda Director, Connected Health





#### Connected Health at Tandem.

To produce value-driven innovation throughout the entire diabetes healthcare ecosystem.



#### t:connect\*

#### **Diabetes Management Application**





# t:connect Mobile A Foundation for Remote Control

Wireless pump uploads.

Health app integration.

Personalization.

Biometric authentication.



Secondary pump display.

Diet, sleep & exercise integration.

Decision support.

#### **Ecosystem Expansion**

Support pump roadmap.

Remotely control pump.

Smartwatch technology.

Data analytics.







#### Billions of data points.

Insulin, CGM, carbs, site change, pump utilization, BG, bolusing.

3.7M cumulative days of combined CGM and insulin therapy data.



Providing customers flexible opportunities to engage with data and HCPs and better self-manage their care.





#### Proven design philosophy.

Simple, easy-to-use products that reduce customer burden and improve the experience.

#### Rapid innovation.

6 product launches in 6 years. Committed to our goal of launching a new product each year.











#### Increased 2018 Sales Guidance

As of	9/25/18	7/30/18
2018 Sales	\$150M - \$158M	\$140M - \$148M
International	\$7M - \$8M	-
Q318 Sales	\$42M - \$44M	-
International	\$2M	-



Solid long-term growth trajectory

Product pipeline.

Renewals.

Animas conversions.

International.



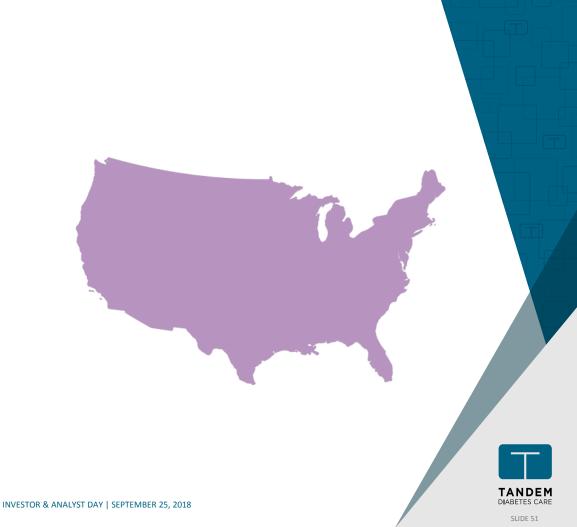




SLIDE 50

Approximately 1.7 million people live with type 1 diabetes in the United States.

Approximately 1.6 million people who live with type 2 diabetes are candidates for pump therapy.



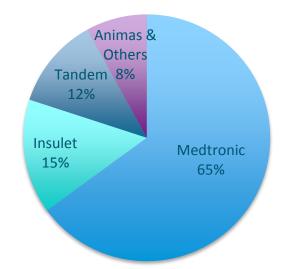


Apx. 70 sales territories calling on healthcare prescribers and people with diabetes.



Domestic Insulin Pump Market Share by Manufacturer\*

Tandem and Medtronic are the remaining domestic durable insulin pump manufacturers.





#### Our customers.

90% have type 1.

Wide age distribution.

Equal mix of women and men.

50% previously used multiple daily injection; 50% converted from a different pump.

40% integrate with CGM.



# Designed for use with or without advanced features







**DON'T USE CGM? NO PROBLEM!** 





SLIDE 55





(Top 2 Box 9 -10)	t:slim X2 n=168	670G n=112
"My pump is easy to use"	70%	38%
"Helps me have good BG control"	60%	44%
"Helps me feel more in control of my diabetes"	57%	39%

All comparisons between Top 2 box scores shown are statistically significant, p < .001



Pump therapy + CGM offers the greatest benefit.





## touch simplicity\*









Advocacy for choice.

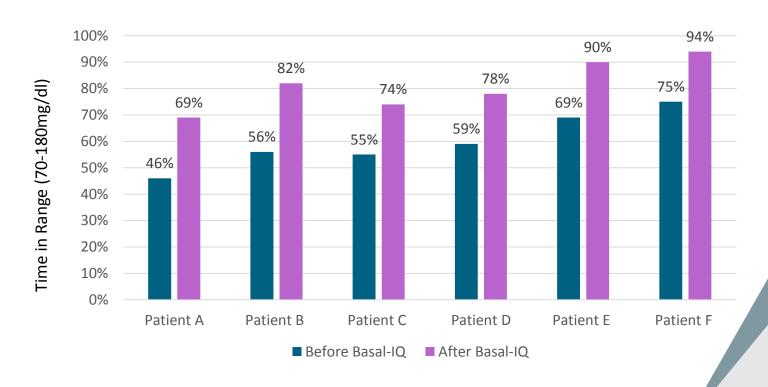
Fewer competitive pump offerings.

Financial position.

Robust data – share in payor cost-savings.



#### Payor X Patient Examples from t:connect





Goal: Grow the U.S. pump market from less than 30% penetration to more than 50%.





# Apx. 42.5 million people OUS with type 1 diabetes.





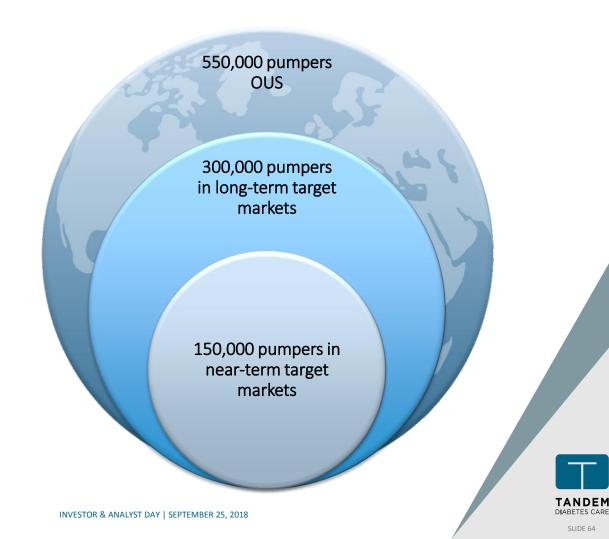


Approximately 3 million people live with type 1 diabetes in our long-term target markets outside the United States.



Our international pump capture opportunity.





Tandem's involvement to support distributors differs in the U.S., Canada, and in other geographies OUS.



#### 5-Year Installed Base Goals:

**Domestic:** Nearly triple from 66,000 today to more than 175,000 customers.

**International:** Grow to more than 50,000 customers.



# Reimbursement differs by product but total amount realized per patient is approximately the same in a four-year reimbursement cycle.

	Domestic	ous
% Distributor	80%	85% - 90%
Pump 1 reimbursed every 4 years	\$4K	\$2K - \$3K
Supplies 120 cartridges and infusion sets used per patient per year	\$4K	\$5K
Total realized per patient at projected near-term distributor mix	\$8K	\$7K - \$8K





Reimbursement.

Sales volume.

Product cost reduction.

Managed expense growth.





#### Manufacturing Facility Capacity

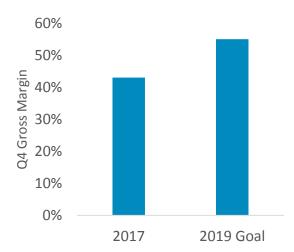




Equipment Lines	2	4
Annual Units	110K	12M
Installed Base Equivalent	N/A	100K
Additional On-Site Equipment Capacity	N/A	2 lines







Historical progress driven by volume, efficiency & reliability.

Longer-term gross margin driven by reimbursement & new products, offset by international.





	Long-term Average Annual Growth Rate
R&D	10%
SG&A	15%



### Key Financial Milestones & Goals

