

Emerging Technologies in Diabetes Management: The Who, What and When for Improving Control

Jodi Strong, DNP, CDE, BC-ADM, CPT
Saturday, February 18, 2017
9:30 a.m. – 10:15 a.m.

There are many emerging technologies that will change the practice of diabetes management. They are demonstrating improved patient and clinician outcomes and provide patients with less disease burden. The quest for noninvasive monitoring and more comprehensive glucose data collection and insulin delivery systems has provided new monitoring and insulin delivery technologies to assist patients, caregivers, and health care professionals to improve diabetes management. Reducing glycemic excursions, hypoglycemia, diabetes related complications, and hospitalizations can lead to improved paid-for-performance measures and reimbursement opportunities for health care organizations and health systems.

This presentation will review some of the newest emerging technologies in diabetes and identify several products that have recently launched, are FDA approved and launching, as well as a few that are coming down the pipeline. This presentation will review several new insulin delivery devices including new or innovative technologies being created by: Tandem Diabetes, Medtronic Diabetes, LifeScan and Companion Medical Inc. Some of the latest products for glucose monitoring devices and software will also be discussed. In addition, a few pipeline products will be reviewed including technologies centered on closed-loop insulin delivery systems and the potential for a glucose sensing contact lens.

References:

1. Abbott (2016, September 28). Abbott Receives FDA Approval for the Freestyle LIBRE PRO™ System, A Revolutionary Diabetes Sensing Technology for Healthcare Professionals to use with their Patients.
2. Abbott Laboratories (2019, October). Freestyle LibrePro: The more you can see, the more you can do. Retrieved from <http://www.freestylelibrepro.us/>
3. American Diabetes Association. Advantages of using an insulin pump. Available at <http://www.diabetes.org/living-with-diabetes/treatment-and-care/medication/insulin/advantages-of-using-an-insulin-pump.html>. December 9, 2013.
4. Anderson S, Raghinaru D, Pinsker J, et al. Multinational Home Use of Closed-Loop Control Is Safe and Effective. *Diabetes Care*. 2016 Jul;39(7):1143-50.
5. Becton , Dickinson & Company (2015, June 8). BD and Medtronic Collaborate to Introduce a New Infusion Set with BD FlowSmart™ Technology Designed to Improve Insulin Pump Therapy: New Innovation Demonstrates Reductions in Flow Interruptions, Including Silent Occlusions. Retrieved from <http://www.bd.com/infusionset/pdfs/BD-MDT-Partnership-Release.pdf>
6. Bolick, N, et al. "Reduction of Silent Occlusion Occurrence During Continuous Subcutaneous Insulin Infusion." *Diab Tech Ther* 2015 (Suppl 1);17:A-35
7. Boris P. Kovatchev, Eric Renard, Claudio Cobelli, et al. Safety of Outpatient Closed-Loop Control: First Randomized Crossover Trials of a Wearable Artificial Pancreas. *Diabetes Care*. 2014 Jul; 37(7): 1789–1796.
8. Companion Medical, Inc. (2016, July 27). Companion Medical Receives FDA Clearance for Smart Insulin Delivery System.
9. DiaTribe (2015, April 16). *Google Secures Patent for Glucose-Sensing Contact Lens*. Retrieved from <https://diatribe.org/google-secures-patent-glucose-sensing-contact-lens>
10. DiaTribe (2014, January, 16). *Glucose Sensing Contact Lenses – Google[x]’s Ambitious Venture into Diabetes*. Retrieved from <https://diatribe.org/issues/60/new-now-next/1>

11. DiaTribe (2015, April 22). Medtronic Announces Major Partnership with IBM and the Watson Supercomputer. Retrieved from <https://diatribe.org/medtronic-announces-major-partnership-ibm-and-watson-supercomputer>
12. DiaTribe (2016, June 28). Medtronic MiniMed 670G Trial Results: 44% Reduction in Hypoglycemia, 0.5% A1c Improvement. Retrieved from <https://diatribe.org/medtronic-minimed-670g-trial-results-44-reduction-hypoglycemia-05-a1c-improvement>
13. Hakami, H. (2016, September 28). FDA APPROVES MINIMED 670G SYSTEM – WORLD'S FIRST HYBRID CLOSED LOOP SYSTEM. Retrieved from <https://www.medtronicdiabetes.com/blog/fda-approves-minimed-670g-system-worlds-first-hybrid-closed-loop-system/>
14. Hoskins, M. Healthline (2016, August 11). Investor Updates: Diabetes Technology Tidbits Mid-2016. Retrieved from <http://www.healthline.com/diabetesmine/investor-updates-diabetes-tech-mid2016#1>
15. IBM (2015, April 13). IBM and Medtronic to Partner to Improve Diabetes Care. Retrieved from http://www.prnewswire.com/news-releases/ibm-and-medtronic-to-partner-to-improve-diabetes-care-300064996.html?utm_source=facebook&utm_medium=organic&utm_content=devices&utm_campaign=news
16. Johnson & Johnson (2016, June 13). New Data Show On-Demand, Mealtime Insulin Delivery System Enabled More than 50 Percent of Patients to Report Improved Dose Compliance: Innovative, In-Development Patch Allows Simple and Discreet Dosing and Greater Patient Satisfaction.
17. Ly T, Buckingham B, DeSalvo et al. Day-and-Night Closed-Loop Control Using the Unified Safety System in Adolescents With Type 1 Diabetes at Camp. *Diabetes Care* 2016 Aug; 39(8): e106-e107.
18. Medtronic (2016, July 20). INTRODUCING GUARDIAN™ CONNECT. Retrieved from <https://www.medtronic-diabetes.com.au/community/blog/edit-blog-entry-introducing-guardian%E2%84%A2-connect>
19. One Drop (n.d.) One drop premium. Retrieved from <https://start.onedrop.today/>
20. One Drop (2016). Living your life (with diabetes). Retrieved from <http://onedrop.today/about/>
21. Pai, A. (2016, April 19). Roche partners with mySugr for Accu-Chek, Logbook app integration. <http://www.mobihealthnews.com/content/roche-partners-mysugr-accu-chek-logbook-app-integration>
22. PR Newswire (2016, April 18). Roche Diabetes Care and mySugr enter into a co-promotion agreement to advance the potential benefits of digital health for people with diabetes. Retrieved from <http://www.prnewswire.co.uk/news-releases/roche-diabetes-care-and-mysugr-enter-into-a-co-promotion-agreement-to-advance-the-potential-benefits-of-digital-health-for-people-with-diabetes-576098821.html>
23. Roche (2016). Accu-Chek Connect: Getting a snapshot of your diabetes just became a lot easier. Retrieved from <https://sites.accu-chek.com/microsites/connect/>
24. Tandem Diabetes Care (2017). The t:slim X2 Upgrade Program. Retrieved from <https://www.tandemdiabetes.com/products/tslim-x2-upgrade-program>
25. Tudiabetes.org. *OmniPod Dash Announced and Timing of Horizon APS Announced*. Retrieved from <http://www.tudiabetes.org/forum/t/omnipod-dash-announced-and-timing-of-horizon-aps-announced/57413>

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Emerging technologies in diabetes management: The Who, What & When for improving control

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Presenter Disclosure Information

Jodi L. Strong, DNP, CDE, BC-ADM, CPT

Research Support: None
 Employee: Ascension Health-Ministry Medical Group
 Board Member/Advisory Panel: Ascensia Diabetes, Novo Nordisk, Sanofi
 Stock/Shareholder: Medtronic Diabetes
 Consultant: American Diabetes Association, Novo Nordisk, Sanofi
 Authorship Support: Sanofi

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Objectives

Discuss new diabetes technologies on the horizon, including recently launched, preparing to launch and products in the pipeline including:

- Identifying new insulin delivery devices,
- Reviewing new glucose monitoring devices & Software/Applications,
- Discussing who is appropriate candidates for such technologies based on ADA's Standards of Medical Care in Diabetes—2017.

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Breakdown of Discussion

Insulin & Other Injectable Delivery Devices <ul style="list-style-type: none"> Tandem's T:slim X2 Medtronic's 630G <ul style="list-style-type: none"> Pro Infusion Set LifeScan's OneTouch Via Companion Medical's InPen Intarcia's GLP-1 mini- pump Omnipod Dash System Future of Closed-Loop Insulin delivery systems 	Glucose Monitoring Devices & Software <ul style="list-style-type: none"> Abbott's Libre Pro One Drop Premium mySugr/Roche integration Dexcom's Touchscreen receiver Sugar.IQ w/Watson Google's Contact Lens
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LifeScan's OneTouch Via 2017

The bolus-only, super slim wearable device holds 200 units of insulin and can be worn for three days.

Squeezing two buttons (including through clothes) — will discreetly deliver a two-unit bolus.

Johnson & Johnson (2016, June 13). New Data Shows On-Demand, Medtime Insulin Delivery System Enabled More than 50 Percent of Patients to Report Improved Dose Consistency, Accuracy, and Development of Painful Blisters and Clothing and Contact Patch Sensation. Retrieved from <http://www.jj.com/bio/medtronic/one-touch-via> (accessed 06/16/17).
 Johnson & Johnson (2016, June 13). New Data Shows On-Demand, Medtime Insulin Delivery System Enabled More than 50 Percent of Patients to Report Improved Dose Consistency. Retrieved from <http://www.jj.com/bio/medtronic/one-touch-via> (accessed 06/16/17).

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Companion Medical's InPen – 2017

The first insulin pen with built-in Bluetooth, enabling dose data to be sent to a phone app automatically. It also calculates & recommends optimal dosing; tracks history & timing of doses; monitors insulin temperature; Displays last dose and insulin-on-board; and reports can be sent to the health care provider.

Companion Medical, Inc. (2016, July 27). Companion Medical Receives FDA Clearance for Smart Insulin Delivery System. Retrieved from <http://www.companion-med.com/news> (accessed 06/16/17).
 Companion Medical (2016, July 27). Companion Medical Receives FDA Clearance for Smart Insulin Delivery System. Retrieved from <http://www.companion-med.com/news> (accessed 06/16/17).

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Intarcia's GLP-1 mini-pump



- Intarcia, recently submitted a New Drug Application to the US FDA for its implantable type 2 diabetes therapy, ITCA 650.
- The novel option continuously releases exenatide (a GLP-1 agonist) over the course of three to six months from a mini-pump – about the size of a matchstick – inserted just under the skin by a healthcare provider in a quick procedure (a matter of minutes).
- Many look forward to having a low hassle, needle-free GLP-1 agonist for type 2 diabetes treatment, since the options currently available involve daily or weekly injections.
- An FDA decision is expected by late 2017.
- However, given the first-of-its-kind innovation behind it's delivery mechanism, the FDA may decide to seek opinions from an Advisory Committee prior to making its decision.

Healthcare Tomorrow (2015, January 20). Intarcia's mini-pump: A needle-free, implantable type 2 diabetes therapy. Retrieved from <http://www.healthcaretomorrow.com/news/intarcia-releases-2017-pat-3-intarcia-calls-collaboration.html>

One Drop: Premium



One Drop Premium (Oct 2016) is a service providing:

- Unlimited test strips,
- Bluetooth-enabled meter (Chrome),
- 24/7 in-app diabetes coaching, and
- A personalized diabetes educational program.

Cost of subscription to the Premium Plan
 Meter: \$99.95 (\$20 off with new subscription)
 Unlimited Strips & Experts:
 Monthly: \$39.95
 Annual Prepaid: \$33.33

One Drop (n.d.). One drop premium. Retrieved from <https://www.onedrop.com/>
One Drop (2016). Living your life (with diabetes). Retrieved from <http://onedrop.today/about>

MySugr Logbook /Accu-Chek Connect Integration – Fall 2016

The partnership allows glucose readings from the Accu-Chek meter to be sent via Bluetooth straight into the world's most popular diabetes app

The MySugr mobile app benefits from multiple integration features, including the ability to sync data for export, and helps patients track their blood glucose throughout the day. It engages patients through gamification mechanics, activities & rewards, and by using a 'monster friend' to show their progress. The app helps estimate A1c scores based on daily measurements of SMBG, focusing primarily on patients using insulin for diabetes management.



Ph. A. (2016, April 15). Roche partners with mySugr for Accu-Chek, Logbook app integration. <http://www.rochehealthcare.com/content/roche-partners-mySugr-accu-chek-logbook-app-integration>
PH Newsroom (2016, April 15). Roche Diabetes Care and mySugr enter into a co-promotion agreement to advance the potential benefits of digital health for people with diabetes. Retrieved from <http://www.roche.com/pressroom/roche-diabetes-care-and-mySugr-enter-into-a-co-promotion-agreement-to-advance-the-potential-benefits-of-digital-health-for-people-with-diabetes-010002621.html>
Roche (2016). Accu-Chek Connect: Getting a snapshot of your diabetes just became a lot easier. Retrieved from <https://usa.accu-chek.com/rocheconnect/>

Sugar.IQ Medtronic/Watson – Late 2016

Sugar.IQ, uses CGM and insulin information from Medtronic integrated pumps & sensors along with IBM Watson's cognitive computing power, combined with Medtronic's expertise in diabetes, to find hidden patterns in diabetes data.

The app provides immediate personalized awareness on a single platform that brings together important data, perspectives & insights.



Diabetes (2016, April 22). Medtronic Announces Major Partnership with IBM and the Watson Supercomputer. Retrieved from <http://www.medtronic.com/pressroom/medtronic-announces-major-partnership-with-ibm-and-the-watson-supercomputer>
IBM (2015, April 15). IBM and Medtronic to Partner to Improve Diabetes Care. Retrieved from <http://www.ibm.com/press/us/2015/ibm-medtronic-partnership-to-improve-diabetes-care-010002621.html>
<http://www.sugar.iq.com/>

ADA Guidelines for pCGM

Use of pCGM in patients with Type 1 DM

- 17,317 participants
- Confirmed that more frequent CGM use is associated with lower A1C.
- Another study showed that children with 70% sensor use (i.e., ≥5 days per week) missed fewer school days.
- Small randomized controlled trials in adults and children with baseline A1C 7.0–7.5% have confirmed favorable outcomes including a reduced frequency of hypoglycemia (defined as BG <70 mg/dL) and maintaining A1C <7% during the study period in groups using CGM, suggesting that CGM may provide further benefit for individuals with type 1 diabetes who already have good glycoemic control

American Diabetes Association (2017, January, p. 549). American Diabetes Association Standards of Medical Care in Diabetes—2017. Retrieved from <http://diabetes.diabetespubs.org/>

Abbott's FreeStyle Libre Pro and FreeStyle Libre (potentially in early 2017).



- The FreeStyle Libre Pro system requires NO fingerstick calibration so patients do not need to be trained by their healthcare professional on calibration
- After the sensor is applied to the arm there is no requirement for the patient to interact with the system
- Provides reliable glucose data. Healthcare professionals receive up to 14 days of continuous glucose data based on uninterrupted, normal daily routines of their patients
- Reduced equipment costs, maintenance and time

Abbott (2016, September 28). Abbott Receives FDA Approval for the FreeStyle Libre Pro™ System, A Revolutionary Diabetes Sensing Technology for Healthcare Professionals to Use with Insulin. Retrieved from <http://www.abbott.com/pressroom/2016/09/28-abbott-receives-fda-approval-for-the-freestyle-libre-pro-system-a-revolutionary-diabetes-sensing-technology-for-healthcare-professionals-to-use-with-insulin>
Abbott Laboratories (2016, October). FreeStyle Libre Pro. The more you can see, the more you can do. Retrieved from <http://www.freestylelibre.com/>

Dexcom's Pipeline

Current Projects

PATIENT CONVENIENCE INITIATIVES

<p>Smaller Transmitter</p> <ul style="list-style-type: none"> Reduction in height and volume 	<p>Simplified Insertion System</p> <ul style="list-style-type: none"> One hand insertion Consistency Major Manufacturing Change 	<p>Connected Receiver</p> <ul style="list-style-type: none"> Touch Screen Connectivity Stronger Signal to Mobile Solution Stick-up for Most Patients
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A smaller transmitter and a new one-button applicator are currently under regulatory (FDA) review (US).

An Android version of the G5 app is currently under FDA review, with launch expected early 2017.

A new touchscreen receiver is currently under FDA review.

An insulin-dosing label claim is hoped for in early 2017. Meaning a confirmatory finger stick test is not required before giving insulin. FDA discussions continue following the positive Advisory Committee meeting in July.

Medicare coverage in 2018?

Holmes, M. Healthline (2016, August 11). Investor Update: Diabetes Technology. <http://www.healthline.com/diabetes/investor-update-diabetes-tech-#d121641>

Dexcom/Verily Sensor Project

G6 Intro



Significant reduction in size of CGM on the body, looking at make it less expensive, and will bring technology to far more people than are currently using it (only about 1-in-5 people with type 1 in the US use CGM).

Will use the G6 sensor and is expected to need no finger stick calibration.

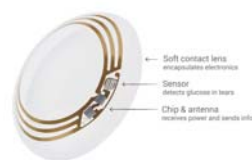
Expected to be approved for making insulin-dosing decisions, and to communicate directly with smartphones via Bluetooth.

A first-gen version (smaller than FreeStyle Libre) is expected in late 2018, while the smaller second-gen version is expected as early as 2020.

Kennedy, L. & Brown, A. (2016, November 20). Dexcom's G6 Sensor Shows in Early Accuracy Study. <https://librify.com/dexcom-g6-sensor-shows-early-accuracy-study>

Google's Role in the Diabetes Market

Google's Glucose Sensing Contact Lenses



The system would likely contain 2 or 3 parts: (i) the contact lens; (ii) a "reader" device, which would communicate and power the lens; and (iii) a user display, to see and review the data.

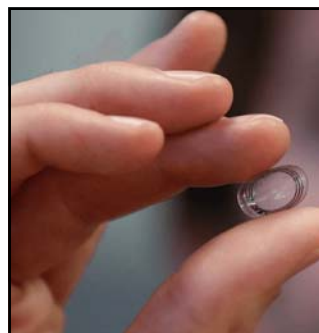
The patent specifically mentions the possibility of eyeglasses, jewelry (e.g., earrings, necklace), or clothing (e.g., a scarf, hat, headband) functioning as the reader. The device however must be close enough to the lens to make sure that the lens can communicate with the reader.

The device could be a smart phone or wearable computer. One example given is a display worn on the head or in front of the eyes, such as Google Glass (another project in the Google[x] division).

DiLiberto (2015, April 16). Google Secures Patent for Glucose-Sensing Contact Lens. Retrieved from <https://librify.com/google-secures-patent-glucose-sensing-contact-lens>

DiLiberto (2014, January, 09). Glucose Sensing Contact Lenses - Google's Android Venture into Diabetes. Retrieved from <https://librify.com/google/android-venture-into-diabetes>

Google's Contact Lens Cont'd...



The patent describes how high and low alarms might work and how continuous data could be displayed, suggesting that Google's ultimate goal may be a CGM-like technology.

The smart contact lens could be the same size as standard contact lenses and could be made of the same (or similar) material. In theory, they might not feel any different to wear than a normal contact lens.

DiLiberto (2015, April 16). Google Secures Patent for Glucose-Sensing Contact Lens. Retrieved from <https://librify.com/google-secures-patent-glucose-sensing-contact-lens>

DiLiberto (2014, January, 09). Glucose Sensing Contact Lenses - Google's Android Venture into Diabetes. Retrieved from <https://librify.com/google/android-venture-into-diabetes>

ADA's Standards of Medical Care in Diabetes—2016: Summary of Revisions

Because of the growing number of older adults with insulin-dependent diabetes, the ADA added the recommendation that people who use continuous glucose monitoring and insulin pumps should have continued access after they turn 65 years of age.



American Diabetes Association (2016, January, Section 5). Standards of Medical Care in Diabetes—2016: Summary of Revisions. <http://www.diabetes.org/standards-of-care>

Medtronic MiniMed Pro Infusion Set with BD FlowSmart technology – 2016.



This infusion set has several key improvements:

- smallest catheter on the market, made of soft pillamer instead of stainless steel
- 28 gauge thickness versus 25 gauge, so a 6mm set would have a 30 gauge needle
- uses "inline infusion pressure" – like low pressure in plumbing, reducing the tendency for blockage/buildup

- the tubing connection swivels, so it can attach in multiple directions and lock in at the angle that's most comfortable
- Available in both Paradigm and Luer Lock versions of the new set so it can be used with many different commercially available systems
- and last not least, IT HAS A SIDE PORT, (or second side hole) that serves as an "ancillary path for fluid" -- an alternate route for the insulin to flow in case the first path is blocked

Medtronic, Johnson & Johnson (2015, June 01, BD and Medtronic Collaborate to Introduce a New Infusion Set with BD FlowSmart™ Technology. Designed to Improve Insulin Pump Therapy. New Innovation Demonstrates Reductions in Flow Interruptions, Including Short Circuits. Retrieved from <http://www.medtronic.com/usa/pressroom/2015/06/01/medtronic-bd-collaborate-to-introduce-a-new-infusion-set-with-bd-flowsmart-technology>

Closing the Loop (or at least the backpack!) We've come along way...

This is a picture of the very first insulin pump from 1963 by Dr. Arnold Kishish. It was worn on the back and was roughly the size of a Marine backpack. Not commercially available due to its size. First wearable pump=1976

Had an insulin pump... Before it was cool



First Insulin Pump (1963). Picture retrieved from <http://13.blogspot.com/2007/11/82G740u8M3PFAAAAAAAAGuG2M7Bkx100700u0p0u0e0v0m7g0p>

Tandem T: Slim's X2 Insulin Delivery System

Oct-Dec 2016. The latest Tandem pump added a new Bluetooth radio and enables software updates to add Dexcom G5 connectivity and automated insulin delivery algorithms. It has the potential to enable users to add new features in the future, independent of their insurance pump replacement cycle. The t:slim X2 Pump also incorporates familiar technology.



Tandem Diabetes Care (2017). The latest X2 Upgrade Program. Retrieved from <https://www.tandemdiabetes.com/products/x2-upgrade-program>

Tandem's Closed Loop Potential



This trial will combine Tandem's t:slim X2 insulin pump, Dexcom's G5 Bluetooth-enabled transmitter and software, and Type Zero's in Control algorithm, into one device, controlled by a smartphone.

It will control the users' insulin by monitoring and adjusting basal rates, giving insulin based on predicted highs, and stepping back on insulin delivery if the user is predicted to go low. The user however will need to manually bolus for meals.

The NIH is funding the new, International Diabetes Closed Loop (IDCL) Trial.

Anderson S, Raghoebari D, Prater J, et al. Multinational Home Use of Closed-Loop Control Is Safe and Effective. Diabetes Care. 2016;39(7):1143-50. <http://www.diabetescare.com/doi/10.2337/130544> Retrieved from Tandem Diabetes Care, Dexcom and TypeZero. Retrieved from <http://www.tandemdiabetes.com/clinical-trials>

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Medtronic's 630G System

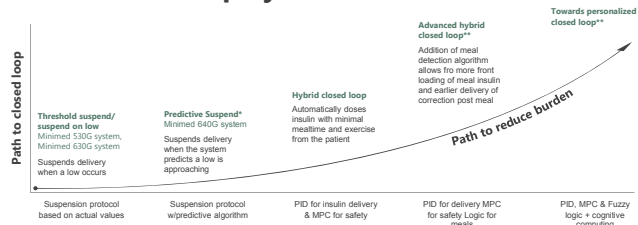
- SMARTGUARD™ TECHNOLOGY
- Takes action to reduce lows* without raising ATC
- Suspend on low feature pauses insulin delivery for up to two hours--so glucose levels can recover
- Exclusive to MiniMed systems
- BOLUS WIZARD® CALCULATOR
- Automatically calculates and recommends precise bolus doses
- Helps your patients avoid insulin stacking
- PREDICTIVE ALERTS
- Prompts patients to take action sooner to prevent lows and keep them in range
- Can be set in 5 minute increments up to 30 minutes
- BUILT-IN CGM
- Wirelessly sends glucose information to the pump every five minutes
- Gives your patients real-time trends for making good treatment decisions



Medtronic Diabetes (2017). MiniMed 630G Insulin Pump System MEET THE 630G CGM SYSTEM - THE NEWEST ADDITION TO THE FAMILY. Retrieved from <http://www.medtronicdiabetes.com/mini630g-insulin-pump-system>

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Medtronic's Algorithms for a Closed Loop System



Medtronic Diabetes (2017, January 8). Medtronic data on file used with permission from Medtronic. Dr. Global Medical Affairs Specialist, Linda Bueland



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Medtronic's 670G Semi-Closed Loop System

U.S. Launch March/April 2017



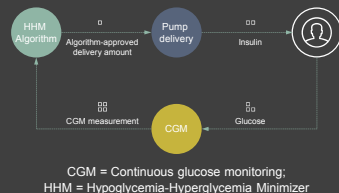
First automated basal insulin delivery system that is FDA approved and will automatically increase/decrease basal insulin delivery in response to CGM information. It's particularly effective overnight

DiNile (2016, June 28). Medtronic MiniMed 670G Trial Results: 44% Reduction in Hypoglycemia, 0.5% A1c Improvement. Retrieved from <https://diabetes.org/medtronic-mini670g-trial-results>

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Animas Hypoglycemia-Hyperglycemia Minimizer

HHM System



CGM = Continuous glucose monitoring;
HHM = Hypoglycemia-Hyperglycemia Minimizer

Timing: A launch is expected in late 2018/early 2019. Animas is still working with the FDA to plan a pivotal trial.

What it looks like: It is a control algorithm built into an Animas pump that talks to a Dexcom CGM. Animas showed the following picture at a business update in May, though the product may have changed since that time.

What the system promises to do: It will adjust insulin delivery to minimize both highs and lows.

Notable features: The pivotal trial is expected to include children as young as two years old.

Finan et al. "Closed Loop Control Performance of the Hypoglycemia-Hyperglycemia Minimizer (HHM) System in a Feasibility Study", Journal of Diabetes Science & Technology, 2014, Vol. 8(1) 35-42.

Omnipod's Dash Insulin Management System

Omnipod Dash is expected to launch by the end of 2017 and will integrate Bluetooth into the body-worn, tubeless pod, and use a transformed, locked down Android smartphone for functions currently performed on the personal diabetes manager (PDM) handheld device.



Tubalinas.org. Omnipod Dash Announced and Timing of Horizon APS Announced. Retrieved from <http://www.tubalinas.org/forum/omnipod-dash-announced-and-timing-of-horizon-aps-announced57413>

Omnipod's Hybrid Closed-Loop Hopeful

Launch is expected in late 2019.

It includes: an Omnipod tubeless patch pump w/ an integrated control algorithm; a Dexcom CGM; and a Bluetooth-enabled wireless Dash handheld PDM (a locked down Android phone w/ cellular turned off).

- The handheld will also talk to a smartphone app to display key data and allow caregivers to remotely monitor.

The system promises to modulate basal insulin delivery. Users will still need to give correction boluses and meal boluses.

The hybrid closed-loop algorithm will be embedded in the pod itself, meaning users can stay in closed loop when the handheld is out of range.

Pediatric approval is a major priority



Tubalinas.org. Omnipod Dash Announced and Timing of Horizon APS Announced. Retrieved from <http://www.tubalinas.org/forum/omnipod-dash-announced-and-timing-of-horizon-aps-announced57413>

ADA's Standard of Care 2017:

ADA's position on use of Sensor Augmented Insulin Pump Systems.

This technology may be particularly useful in insulin-treated patients with **hypoglycemia unawareness** and/or **frequent hypoglycemic episodes**.

- Although studies have not shown consistent reductions in severe hypoglycemia.

The Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial of 247 patients with type 1 diabetes and documented nocturnal hypoglycemia showed that **sensor-augmented insulin pump therapy with a low glucose suspend function significantly reduced nocturnal hypoglycemia** over 3 months without increasing A1C levels.

Diabetes Care (2017). The 14th X2 Upgrade Program. Retrieved from <https://www.diabetes.org/products/14th-x2-upgrade-program>

Closing the Loop in Insulin Delivery Systems: No artificial physiology about it!

The development of an artificial pancreas for the treatment of insulin-dependent diabetes has been a highly anticipated endeavor for patients, health care providers, scientists, and engineers alike.

Recent progress in research and algorithm technology, together with aspects of β -cell physiology are leading to normal glucose homeostasis. Algorithms continue to be evaluated for their ability to deliver insulin, to recreate, as closely as possible, glucose and insulin profiles observed in healthy individuals.

Emphasis is placed upon how the algorithms compare to the β -cell's secretory response, specifically first-phase and second-phase insulin secretion and glucagon response.

Experimental closed-loop data employing intravenous and subcutaneous glucose sensors and implanted and external insulin pumps

L. T. Buckingham, B. Dolan et al. Day and Night Closed Loop Control Using the Unified Safety System in Adolescents With Type 1 Diabetes at Camp. Diabetes Care 2016 Aug; 39(8): e106-e107.

Advancements in the Artificial Pancreas (AP)

Biostat: The Artificial Pancreas 1977

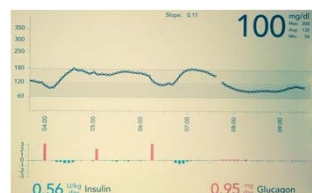


The Artificial Pancreas 2010



Diabetes Library 13, 2017. Used with permission from Thomas C. Walker, DNP, APRN, BC-ADM, CDE, Director, Clinical Programs, Dexcom Inc.

Advancements in the Artificial Pancreas (AP)



5-day experiments in adolescents with Type 1 Diabetes
 Randomized cross-over design
 5 days on bionic pancreas

5 days usual care
 Study and camp staff provide 24-hour coverage to monitor glycemia

Diabetes (January 13, 2017). Used with permission from Tanya C. Wilster, DNP, APRN, BC-ADM, CDE, Director, Clinical Programs, Dexcom, Inc.

Beta Bionics: Dual Chambered Pump

iLet Bionic Pancreas



- The latest design is thinner and with a much lower power display, closer to what is planned to eventually launch. It has a 3.2-inch screen with higher resolution, with a black and white LED display.*
- It will also have the Dexcom G5 CGM integrated inside.
- Also developed a proprietary infusion set, which has two needles and dual-tubing but will require only a single insertion for both glucagon and insulin delivery.

Tanberich, A. & Hawkins, M. (2016, December 22). Healthline: The Year in Diabetes: Looking Back on 2016. Retrieved from <http://www.healthline.com/diabetes/year-in-review-2016/>

Free Living Home Use of an Artificial Beta Cell

Adults (AP@home04) Poster 987, EASD 2015

Three European centers; UK, Germany, Austria

33 Adults with T1DM with HbA1c between 7.5% and 10% on CSII

Dedicated 4 week optimization period prior to randomization

Day and night hybrid closed-loop for 3 months

Children and adolescents (APCam08)

Three UK centers, Cambridge, London, Leeds

25 children and adolescents with T1DM aged 6 to 18 years with HbA1c below 10% on CSII

2-8 week run-in period and optimization

Overnight closed-loop for 3 months

Poster Publication AP@home04, Lestratekha, Hovorka et al on behalf of AP@home consortium. BMJ Open 2014;4:e006075
 Thank, Hovorka et al on behalf of AP@home consortium. Poster 987, EASD 2015
 Thank, Tanberich, Hovorka et al on behalf of APCam consortium and AP@home consortium, NEJM Sep 2015

Who, What & When do we owe?



We are privileged to serve individuals living with diabetes and are eager to collaborate with the technology community to help us meet our goal of improving the lives of those affected by the disease. By convening this influential group of like-minded innovators, our goal is to advance technology solutions that go beyond this event and create true impact for individuals living with diabetes.

- Jane Chiang, MD, executive vice president, medical innovation for the American Diabetes Association

American Diabetes Association. (2016, November 4). Quote from Jane Chiang, MD. American Diabetes Association. Retrieved from <http://www.diabetes.org/newsroom/press-releases/2016/november-4-diabetes-association-launches-2016/>

But Remember
 We Still Have no CURE!!



The End
Thank You !
 Dr. Jodi Strong, DNP, CDE, BC-ADM, CPT
 Jodi.strong@ascension.org



References

- Abbott (2016, September 28). Abbott Receives FDA Approval for the FreeStyle LIBRE PRO™ System, A Revolutionary Diabetes Sensing Technology for Healthcare Professionals to use with their Patients. Retrieved from <http://abbott.mediaroom.com/2016-09-28-Abbott-Receives-FDA-Approval-for-the-FreeStyle-Libre-Pro-System-a-Revolutionary-Diabetes-Sensing-Technology-for-Healthcare-Professionals-to-Use-with-their-Patients>
- Abbott Laboratories (2019, October). FreeStyle LibrePro: The more you can see, the more you can do. Retrieved from <http://www.freestylelibrepro.us/>
- American Diabetes Association (2016, January, Section 5). Standards of Medical Care in Diabetes—2016: Summary of Revisions. Diabetes Care 2016;39(Suppl. 1):S4–S5. DOI: 10.2337/dc16-S003.
- American Diabetes Association (2017, January, p. S49). American Diabetes Association Standards of Medical Care in Diabetes—2017. Retrieved from care.diabetesjournals.org.
- American Diabetes Association. (2016, November 4, Quote from Jane Chiang, MD.) American Diabetes Association Convened Leaders from the Intersection of the Diabetes and Technology Ecosystems at its First-Ever Technology Summit – Retrieved from <http://www.diabetes.org/newsroom/press-releases/2016/american-diabetes-association-tech-summit.html>
- Anderson S, Raghinaru D, Pinsky J, et al. Multifunctional Home Use of Closed-Loop Control Is Safe and Effective. Diabetes Care. 2016 Jul;39(7):1143-50.
- Beclon, Dickinson & Company (2015, June 8). BD and Medtronic Collaborate to Introduce a New Infusion Set with BD FlowSmart™ Technology Designed to Improve Insulin Pump Therapy: New Innovation Demonstrates Reductions in Flow Interruptions, Including Silent Occlusions. Retrieved from <http://www.bd.com/infusionsets/pdfs/BD-MDT-Partnership-Release.pdf>
- Bolsik, N, et al. "Reduction of Silent Occlusion Occurrence During Continuous Subcutaneous Insulin Infusion." Diab Tech Ther 2015 (Suppl 1):17A-35

References

- Businesswire (2016, November 10). NIH-funded International Diabetes Closed Loop (IDCL) Trial to Combine Technologies from Tandem Diabetes Care, Dexcom and TypeZero. Retrieved from <http://www.businesswire.com/news/home/20161110005482/en/NIH-funded-International-Diabetes-Closed-Loop-IDCL-Trial>
- Companion Medical, Inc. (2016, July 27). Companion Medical Receives FDA Clearance for Smart Insulin Delivery System. Retrieved from <http://www.prnewswire.com/news-releases/companion-medical-receives-fda-clearance-for-smart-insulin-delivery-system-300304933.html>
- Dexcom (January 13, 2017). Used with permission from Tomas C. Walker, DNP, APRN, BC-ADM, CDE, Director, Clinical Projects, Dexcom Inc.
- Dexcom Inc. (January 13, 2017). From primary source, Ed Damiano, Boston University. Used with permission from Tomas C. Walker, DNP, APRN, BC-ADM, CDE.
- Diabetes Daily (2016, November 10). NEWS: Tandem, Dexcom, and Type Zero Technologies to Combine in Closed Loop Trial. Retrieved from [file:///C:/Users/jstrong/Downloads/diabetesdaily.com-NEWS%20Tandem%20Dexcom%20and%20Type%20Zero%20Technologies%20to%20Combine%20in%20Closed%20Loop%20Trial.pdf](http://www.diabetesdaily.com/NEWS%20Tandem%20Dexcom%20and%20Type%20Zero%20Technologies%20to%20Combine%20in%20Closed%20Loop%20Trial.pdf)
- Diatribe (2015, April 16). Google Secures Patent for Glucose-Sensing Contact Lens. Retrieved from <https://diatribe.org/google-secures-patent-glucose-sensing-contact-lens>
- Diatribe (2014, January, 16). Glucose Sensing Contact Lenses – GoogleX's Ambitious Venture into Diabetes. Retrieved from <https://diatribe.org/issues/60/new-now-need1/>
- Diatribe (2015, April 22). Medtronic Announces Major Partnership with IBM and the Watson Supercomputer. Retrieved from <https://diatribe.org/medtronic-announces-major-partnership-ibm-and-watson-supercomputer/>
- Diatribe (2016, June 28). Medtronic MiniMed 670G Trial Results: 44% Reduction in Hypoglycemia, 0.5% A1c Improvement. Retrieved from <https://diatribe.org/medtronic-minimed-670g-trial-results-44-reduction-hypoglycemia-05-a1c-improvement/>

References

- Frian et al. "Closed Loop Control Performance of the Hypoglycemia-Hyperglycemia Minimizer (HMM) System in a Feasibility Study", Journal of Diabetes Science & Technology 2014, Vol. 8(1) 35-42.
- First Insulin Pump (1963). Picture retrieved from http://1.bp.blogspot.com/_xsoh1a8Sg8T/42uUfKMPfAAAAAABAAgA/wuU2GN9BtBk/s1600/insulinpumpseventyeight.jpg
- Hakami, H. (2016, September 28). FDA APPROVES MINIMED 670G SYSTEM – WORLD'S FIRST HYBRID CLOSED LOOP SYSTEM. Retrieved from <https://www.medtronicdiabetes.com/blog/fda-approves-minimed-670g-system-worlds-first-hybrid-closed-loop-system/>
- Hoskins, M. Healthline (2016, August 11). Investor Updates: Diabetes Technology Tidbits Mid-2016. Retrieved from <http://www.healthline.com/diabetes/mile/investor-updates-diabetes-tech-mid2016#1>
- IBM (2015, April 13). IBM and Medtronic to Partner to Improve Diabetes Care. Retrieved from http://www.prnewswire.com/news-releases/ibm-and-medtronic-to-partner-to-improve-diabetes-care-300064996.html?utm_source=facebook&utm_medium=organic&utm_content=devices&utm_campaign=news
- Intarcia Therapeutics (2017, January 9). Intarcia and Calbr Announce Collaboration and In-Licensing Deal Aimed at Delivering a Next Generation Combination Product for Diabetes and Obesity. Retrieved from <https://www.intarcia.com/media/press-releases/2017-jan-9-intarcia-calbr-collaboration.html>
- Johnson & Johnson (2016, June 13). New Data Show On-Demand, Mealtime Insulin Delivery System Enabled More than 50 Percent of Patients to Report Improved Dose Compliance: Innovalve, In-Development Patch Allows Simple and Discreet Dosing and Greater Patient Satisfaction. Retrieved from <https://www.jj.com/media-center/press-releases/new-data-show-on-demand-mealtime-insulin-delivery-system-enabled-more-than-fifty-percent-of-patients-to-report-improved-dose-compliance>
- Kennedy, L. & Brown, A. (2016, November 26). Dexcom's G6 Sensor Shines in Early Accuracy Study. Diatribe. Retrieved from <https://diatribe.org/dexcom-g6-sensor-shines-early-accuracy-study>
- Ly T, Buckingham B, DeSato et al. Day-and-Night Closed-Loop Control Using the Unified Safety System in Adolescents With Type 1 Diabetes at Camp. Diabetes Care 2016 Aug; 39(8): e106-e107.

References

- Medtronic (2016, July 20). INTRODUCING GUARDIAN™ CONNECT. Retrieved from <https://www.medtronic-diabetes.com.au/community/blog/diit-blog-entry-introducing-guardian%20%26%20connect>
- Medtronic Diabetes (2017, January 8). Medtronic data on file used with permission from Medtronic Sr. Global Medical Affairs Specialist, Linda Burkett.
- One Drop (n.d.). One drop premium. Retrieved from <https://start.onedrop.today/>
- One Drop (2016). Living your life (with diabetes). Retrieved from <http://onedrop.today/about/>
- Pai, A. (2016, April 19). Roche partners with mySugr for Accu-Chek, Logbook app integration. <http://www.mobhealthnews.com/content/roche-partners-mysugr-accu-chek-logbook-app-integration>
- PR Newswire (2016, April 18). Roche Diabetes Care and mySugr enter into a co-promotion agreement to advance the potential benefits of digital health for people with diabetes. Retrieved from <http://www.prnewswire.co.uk/news-releases/roche-diabetes-care-and-mysugr-enter-into-a-co-promotion-agreement-to-advance-the-potential-benefits-of-digital-health-for-people-with-diabetes-376098821.html>
- Roche (2016). Accu-Chek Connect: Getting a snapshot of your diabetes just became a lot easier. Retrieved from <https://sites.accu-chek.com/microsites/connect/>
- Tandem Diabetes Care (2017). The tslim X2 Upgrade Program. Retrieved from <https://www.tandemdiabetes.com/products/tslim-x2-upgrade-program>
- Tenderich, A. & Hoskins, M. (2016, December 22). Healthline: The Year in Diabetes: Looking Back on 2016. Retrieved from <http://www.healthline.com/diabetes/mile/year-review-2016#5>
- Tudabetes.org. OmniPod Dash Announced and Timing of Horizon APS Announced. Retrieved from <http://www.tudabetes.org/forum/omnipod-dash-announced-and-timing-of-horizon-aps-announced/57413>