TechTok: The Latest in Closed Loop Systems with Insulin Pumps and Advance Features

Nebraska Medicine Diabetes and Endocrinology Center
By Geri McVey, BSN, RN, CDCES, CPT

Nebraska Medicine
SERIOUS MEDICINE. EXTRAORDINARY CARE.

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IN THE LIFE OF DIABETES:

tech tok

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Conflict of Interest and Resources

- I have no actual or potential conflict of interest in relation to this presentation.
- Technology field for Insulin pumps and CGMs is rapidly changing. As a result, adoption of these technologies is gradually rising.

- **Resources:**

- 1.Draznin B, Aroda VR, Bakris G, Benson G, Brown FM,Freeman R, Green J, Huang E, Isaacs D, Kahan S, Leon J.7.Diabetes Technologoy: Standards of Medical Care in Diabetes 2022. Diabetes Care.2022 Jan 1:45(Supplement_1):597-112. https://www.niddk.nih.gov/health-information/diabetesoverview/managing-diabetes/continuous-glucose-monitoring
- 2.Peters A. Improvement in HbA1C after 8 weeks of Omnipod 5® Automated Insulin Delivery System use in adults with Type 2 diabetes: From injections to hybrid closed-loop therapy. Presented at: Advanced Technologies & Treatments for Diabetes 2022; Barcelona, Spain; April 27-30, 2022. Poster 002.
- 3.Coby EC, Berget C, Messer LH, Forlenza GP. Review of the Omnipod 5 Automated Glucose Control System Powered by Horizon for the treatment of Type 1 diabetes. Ther Deliv. 2020; 11 (8):507-519
- 4.U.S. Food and Drug Administration-last updated 3/29/22
- .5. Hinemann L, Schoemaker M, Schmelzeisen-Redecker G, et al. Benefits and Limitations of MARD as a Performance Parameter for Continuous Glucose Monitoring in the Interstitial Space. Journal of Diabetes Science and Technology. 2020 Jan;14(1):135-150. DOI: 10.1177/1932296819855670. PMID: 31216870; PMCID: PMC7189145.
- 6. Klonoff DC, Parkes JL, Kovatchev BP, Kerr D, Bevier WC, Brazg RL, Christiansen M, Bailey TS, Nichols JH, Kohn MA. Investigation of the Accuracy of 18 Marketed Blood Glucose Monitors. Diabetes Care. 2018 Aug;41(8):1681-1688. doi: 10.2337/dc17-1960. Epub 2018 Jun 13. PMID: 29898901.
- 7. Danne T, Nimri R, Battelino T, Bergenstal RM, Close KL, DeVries JH, et al. International Consensus on Use of Continuous Glucose Monitoring. Diabetes Care. 2017 Dec;40(12):1631-1640. doi: 10.2337/dc17-1600. PMID: 29162583; PMCID: PMC6467165.
- 8. Klonoff DC, Parkes JL, Kovatchev BP, Kerr D, Bevier WC, Brazg RL, Christiansen M, Bailey TS, Nichols JH, Kohn MA. Investigation of the Accuracy of 18 Marketed Blood Glucose Monitors. Diabetes Care. 2018 Aug;41(8):1681-1688. doi: 10.2337/dc17-1960. Epub 2018 Jun 13. PMID: 29898901.
- 9. Pinster JE, Lee JB, Dassau E, et al.. Randomized crossover comparison of personalized MPC and PID control algorithms for the artificial pancreas. *Diabetes Care* 2016;39:1135–1142
- 10. Lewis D.History and perspective on DIY closed looping. J Diabetes Sci Technol.2019:13 (40):790-793. Doi:10.1177/1932296818808307. [PMC free article] [PubMed] [CrossRef] [Google Scholar].
- 11. Messer, L, Berget, C., Forlenza, G. MD. A Clinical Guide to Advanced Diabetes Devices and Closed-Loop Systems Using the CARES Paradigm. Diabetes Technol Ther. 2019 Aug 1; 21(8): 462-469. Doi:10.1089/dia.2019.0105.
- 12. Kadish, AH. A Servomechanism for Blood Sugar Control. BioMedi Sci Instrum (1963(1:171-76.
- 13. Lewis, D. Setting Expectations for Successful Artificial Pancreas/Hybrid Closed loop/Automated Insulin Delivery Adoption. Journal of Diabetes Science and Technology 12 (2):533-534.

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Learning Objectives:

- Explain the pros and cons of utilizing a hybrid closed-loop system
- Differentiate between the various hybrid closed loop systems
- Assess patient safety and outcomes when a hybrid closed loop system is utilized.
- Detail strategies for teaching patients to maximize safety and outcomes with hybrid closed-loop systems.
- Understanding the different types of pump reports for the hybrid closed-loop systems.

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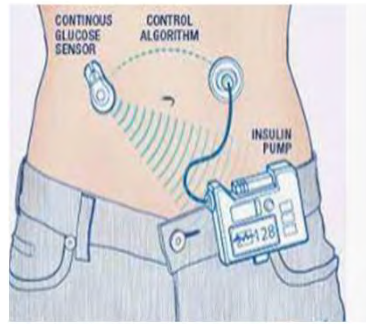
ADA Standard 7-Diabetes Technology-2022

- Diabetes technology is defined as the hardware, devices and software that people with diabetes use to help self-manage their diabetes and improve quality of life.
- The type(s) and selection of devices should be individualized based on a person's specific needs, desires, skill level and availability.
- Diabetes technology, when coupled with education and follow-up, can improve the lives and health with diabetes.
- With the complexity and rapid change of the diabetes technology can also be a continued barrier to patient and provider implementation.



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Diabetes and Technology:

- Living with diabetes is a significant responsibility for our patients. We, as healthcare providers, need to realize that it affects all aspects of a person's life and health and can feel like a never-ending task.
- As technology advances, new products are available to help patients with diabetes. A hybrid closed-loop insulin pump is a new tool to manage the disease and make life a bit easier for people living with diabetes.
- Our bodies are designed with a closed-loop communication between sensors that check blood sugar levels and the pancreas, which responds to these levels using the hormones insulin and glucagon. Insulin lowers blood sugar levels while glucagon raises it.
- It's helpful to think of the foot pedals in a car: the gas and the brake. Insulin acts like the brakes and lowers blood sugar. Glucagon is like the gas pedal and raises blood sugar.

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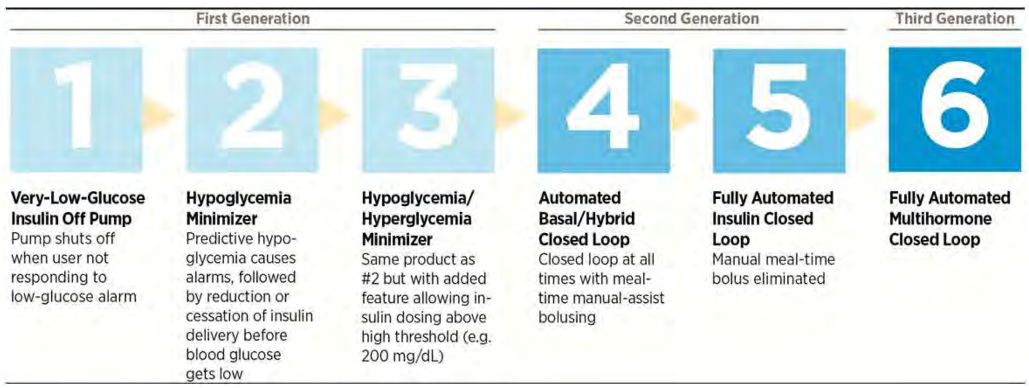
6 categories as defined by JDRF



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Impact of Advanced Technology:

- Closed-loop insulin pump technology has been a true game-changer for people with type 1 and type 2 diabetes.
- Today there are manufacturer-designed looping systems and "do it yourself" systems that are fueled by the diabetes community.
- How these automated insulin delivery systems (AIDs) perform in real life demonstrates their potential to lighten the hour-by-hour burden of insulin and BS management for those living with diabetes.
- There have been plenty of patients moving to the closed-loop systems from either injections or another insulin pump Huge improvements have been made in Hemoglobin A1C results and increase time in range.

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Diabetes Technology

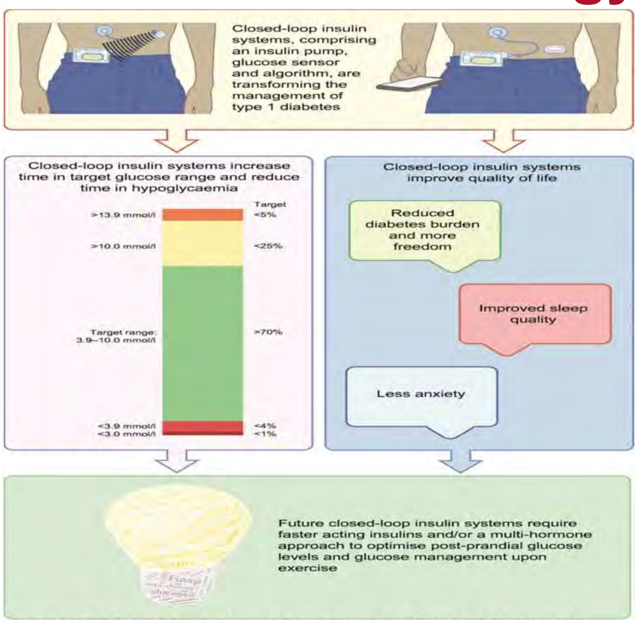

Image sources: Time in range bar copyright American Diabetes Association, 2019 (Battelino et al, Clinical targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range, Diabetes Care, https://doi.org/10.2337/dci19-0028. Copyright and all rights reserved. Material from this publication has been used with the permission of American Diabetes Association; lightbulb created in https://wordart.com

Benefits:
-Type 2 patients use as well
•Regulate/adjust basal insulin delivery automatically
•Compensate for bolus inequities
•Prevent/minimize hypoglycemia
•Fix/minimize hyperglycemia
•Decrease in DKA hospitalizations
•Increase TIR by at least 10%

Considerations for patients:
•Comfort with technology and adjusting. Example: Type 1 for 40+ years, makes own adjustments. May feel like they are losing control.
•Tube or tubeless
•Existing CGM system
•Interface design

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Closed-Loop Systems

- There are over 400 proposed closed-loop algorithm, but only 5 have been FDA approved and implemented by manufacturers.
- Advanced diabetes devices are insulin pumps that integrate with CGMS and contain algorithms that change insulin delivery in response to CGM levels.
- "The effect of closed loop is evident almost immediately after system initiation," explained Stuart Weinzimer, MD. "But appears to be stable thereafter without further gradual improvement." -11
- However, noted that the longer the patient stays in the automated system the increase TIR.
- The increased safety and protection from hypoglycemia during sleep and physical activity have reduced the worry and emotional burdens on the entire family .
- While many providers and diabetes educators are confident with traditional insulin pump therapy and glucose sensors, advanced diabetes devices represent a new class of insulin pump therapy and additional training may be needed for staff and patients.-11

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Providers Role:

- Complex and rapid changes in technology may lead to confusion, misunderstanding and inappropriate clinical decisions, even for those who are experienced..
- Can be difficult to decipher what each of the closed-loop systems do and distinguish the differences (features) and similarities between the devices.
- Providers must comprehend the different "clinical rules" that apply to the different systems and what settings can/cannot be modified.
- Assists with optimizing device settings, deliver competent education, troubleshooting the system, and setting expectations.
- Helpful to have nurses/educators that are trained on the devices to further assist the providers and patients.

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CARES Paradigm :

- Understanding how a system calculates insulin delivery.
- Highlighting fundamental components that may be clinically relevant.
- Adjust insulin dosing parameters to optimize the system
- When to revert to traditional pump mode.
- Education tips for system use.
- CGM sensors and remote monitoring capabilities

Reference 11

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CARES PARADIGM:

C-Calculate	How does the algorithm calculate insulin delivery?	Which components of insulin delivery are automated	(e.g. basal suspensions and modulation, high glucose corrections, food boluses, etc.)?
A-Adjust	How can the user adjust insulin delivery?	Which parameters can be adjusted to influence insulin delivery during automation (example above)?	Which parameters are fixed?
R-Revert	When should the user choose to revert to open-loop/no automation?	When will the system default to open-loop/no automation?	
E-Educate	What are the key education points for the advanced diabetes device (e.g. essential training, tips and tricks, best practices, etc.)?	How does the user optimize time using the automated features?	Where can users and clinicians find additional education?
S-Sensor/Share	What are relevant sensor characteristics for each device	(e.g. calibration and therapeutic BG requirements, duration of sensor wear, etc.	What are the systems capabilities for remote monitoring and closed-based data sharing?

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Automated Insulin Delivery (AID) Systems

- **AIDS systems adjust insulin based on CGM reported glucose levels.**

CGM data receiver and display with insulin delivery system

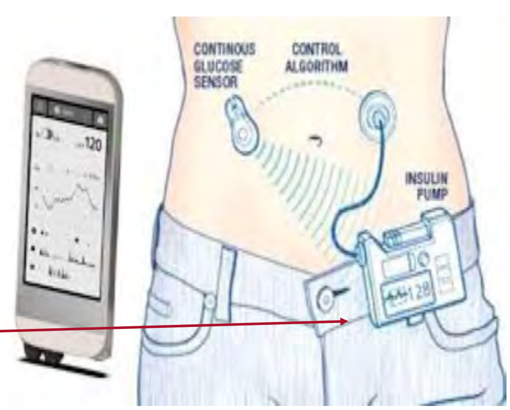
Algorithm

Control Algorithm

$$P \quad K_p e(f)$$

$$I \quad K_i \int_0^1 e(t)dt$$

$$D \quad K^d \frac{de(t)}{dt}$$



Resource #1

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Pumps Involve a Higher Level of Diabetes Care

- Patient and Family Commitment and learning
- Counting carbohydrates
- Calculating insulin doses
- Understanding rapid acting insulin
- Understanding the Algorithm of the HCL device

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In a hybrid closed loop or artificial pancreas system, the algorithm adjusts the basal (background) insulin every few minutes as necessary, to keep the glucose within a target range. At mealtimes, the user counts their carbohydrate and keys it in to the algorithm, which then decides how much insulin is required and sends an instruction to a pump to deliver the dose.

This technology has progressed in the last 10 years:

- first came an insulin pump with low glucose suspend when CGM detects hypoglycaemia,
- next there was predictive low glucose suspend when CGM detects glucose is falling towards hypoglycaemia,
- current systems available are called hybrid closed loop – predictive high and low minimiser work alongside an automated basal rate (though some systems require a programmed basal rate as a starting point) but meal-time boluses must be programmed manually,
- in the future we look forward to having fully automated closed loop with insulin only – needs no programming by the user,
- and eventually fully automated closed loop with insulin and glucagon.

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A closed-loop system is a more sophisticated system, with a control algorithm adjusting insulin delivery (up and down) in response to real-time sensor glucose levels and other inputs, such as meal intake (Fig. 3). The algorithm can accommodate variability of insulin requirements between and within individual users, and account for limitations of CGM accuracy and imprecisions of subcutaneous insulin delivery. Adaptation of the control algorithm to changes in physiological conditions with real-time adjustment of closed-loop control parameters is beneficial for optimal performance. Several different types of control algorithm have been developed, including model predictive control (MPC) algorithms, proportional integral derivative (PID) controllers and fuzzy logic control approaches [4]. MPC algorithms calculate insulin delivery by minimising the difference between model-predicted glucose concentrations and target glucose over a pre-specified prediction time horizon. PID controllers adjust insulin delivery by assessing glucose excursions from three perspectives: (1) deviation from target glucose (proportional component); (2) area under the curve between measured and target glucose (integral component); and (3) rate of change of measured glucose (derivative component). The fuzzy logic approach modulates insulin delivery based on approximate rules to express empirical knowledge of diabetes practitioners.

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Pramlintide is an analogue of amylin, which is co-secreted with insulin from beta cells and reduces postprandial glucose excursions by slowing gastric emptying [23]. A novel dual-hormone closed-loop system delivering a fixed ratio of pramlintide:insulin was evaluated during a 24 h inpatient study in adults with type 1 diabetes. The dual-hormone system improved time in target range compared with an insulin-alone system (84% vs 74%), an effect attributable to improved daytime glucose control [24]. Gastrointestinal symptoms were reported more frequently during use of closed-loop systems with pramlintide as compared with insulin only. Pramlintide co-delivery may support the development of fully closed-loop systems, obviating the need for manually initiated prandial insulin delivery.

Training considerations

High quality user and healthcare professional training is essential for ensuring that the clinical benefits of hybrid closed-loop systems are realised in the real-world setting. This is an important consideration for health economic analyses, to support adoption, implementation and reimbursement. Establishing realistic expectations of hybrid closed-loop therapy and reiterating the importance of core diabetes skills and tasks is important to promote long-term use and optimal clinical outcomes. Training programmes have been developed, using online and face-to-face approaches, to support users to maximise glycaemic and quality-of-life benefits of closed-loop therapy [25].

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Insulin pump considerations:5

- Goal is to keep blood sugars as close to normal as possible/prevent long term complications.

- Ask these questions,
  - Why pump therapy?
  - What are your patients' not getting now?
  - Would they become self-conscious?
  - Would your patients be able to handle the pump at work, traveling, physical activity?
  - What should the family's job/role with the pump?

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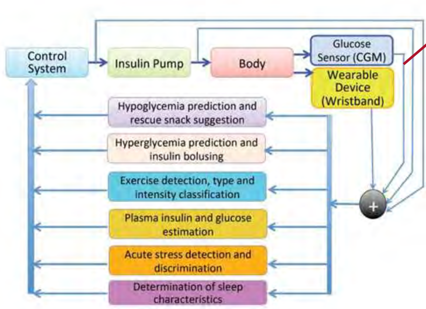
AID ALGORITHM

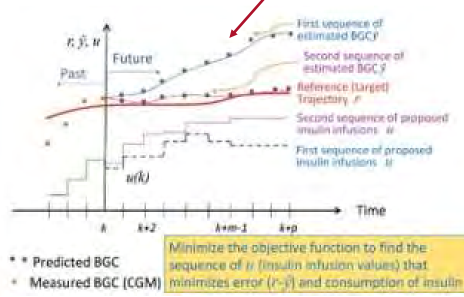
Each device has a different mathematical model for the calculation for the predicted glucose and the required insulin delivery to treat glucose target or range.

EXAMPLES

PROPORTIONAL INTEGRATIVE DIFFERENTIAL (PID)

MODEL PREDICTIVE CONTROL (MPC)





Images: Reference 9

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Key Factors of AID Algorithm for Providers to Understand :

- How each system calculates insulin delivery
- What parameters can be adjusted
- What type of adjustments can be made with closed loop systems
- When should you revert to open loop or manual mode
- Key Education points for patients and healthcare providers.

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Special Circumstances 6

- Visual Acuity - bigger letters, color screen.
- Dexterity
- Lifestyle – sports, shift workers, active traveling.
- Skin Issues- sensitivity to tape (skin irritation).

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Continuous Glucose Monitoring (CGM) 7

- CGM should be considered in children to adults.
- Useful tool in those with frequent hypoglycemia or hypoglycemia unawareness.
- Measures percent of time in, above and below range.
- Real-time data.
- A1C improvements.
- Up to 5–10 minutes lag between blood glucose and interstitial glucose readings.
- Warnings of rapid glucose changes.
- Significant reductions in hypoglycemia Type 1-*
    - 38% reduction of overall hypo and 40% of nighttime hypo
- Type 2 less hypo too-*
    - 43% reduction overall hypo and 54% in nighttime hypo

*AADE Practice Paper, The Diabetes Educator Role in Continuous Glucose Monitoring, July 2018

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Getting your patients started: HCL

- Education appointments are scheduled with education for training on their devices.
- **Initial education covered:**
    - How insulin pump/CGM system works, insulin dosing, noting trends and high/low blood sugars and special features of the system.
    - Each session is individualized so the automated system may start at first visit or on the return visit 3 days after pump start.
- **Follow up education covered:**
    - Review any questions that the patients may have. Education on interpretation of the CGM/hcl reports and what type of adjustments may need to be made.

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Nurses/Educators Role with HCL Systems:

- Diabetes Educators assist with downloading, interpretation, education and patient empowerment
- **Teaching Points**
    - Sensor/infusion site and insertion
    - Difference between interstitial glucose reading and BG
    - Understanding CGM data and trends-Connecting to all available resources
    - Understanding the algorithm and what type of adjustments can be made
    - How to handle the pump in life situations (ex. Before medical procedures put temp target, exercise or activity mode).
    - Teach how to handle meals that are high in both carbs and/or fat and protein

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Education Tips for Patients 8:

- Teach how to respond to CGM arrows, trends, and insulin on board with a closed-loop compared to other pumps.
- Help patients make alarms actionable to prevent alarm fatigue
    - Minimize alarms to only those that require immediate attention to start
    - Treating hypoglycemia with fewer carbs to prevent rebound highs
    - Consider starting with only alerts for hypoglycemia
    - Add hyperglycemia alerts at higher level-250 to start.

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Education Tips continued 9:

- Teach patients the risks of trying to "trick" system increases BS fluctuations and decreases the system's ability to perform properly.
  - Entering fake carbs, overriding bolus calculations, taking extra insulin outside of the system
- Teach patients how to handle specific life situations (sick days, exercise, pregnancy)
- If HCL is disconnected, you should **suspend** insulin delivery.
- When to use the special features of the closed loop systems-temp target/activity and sleep mode

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Clinical Indications for Insulin Pump 10

- Connected with medical team
- Not reaching targets despite Multiple Daily Injections (MDI) and elevated A1C
- Dawn Phenomenon/Somogyi Affect
- Excessive glucose variability
- Irregular / variable schedule
- Monitors BG 4 times a day (or uses CGM)
- Preconception planning and pregnancy
- Frequent hypo or hypo unawareness, nocturnal hypoglycemia
- Extreme insulin sensitivity
- Renal transplantation
- Needle aversion
- Gastroparesis, nephropathy, and early neuropathy

AADE Practice Paper 2018-Continuous Subcutaneous Insulin Infusion (CSII) Without and with Sensor Integration.

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Assessment Criteria to Continue Automated Insulin Delivery System

Impaired level of consciousness or confusion (ex.dementia)
Critical illness requiring intensive care
Diabetes Ketoacidosis or Hyperosmolar Hyperglycemic State (several hospital admissions)
Psychiatric Illness or suicidal ideation
Patient unable to use hands and/or physicallymanipulate pump due to medical condition
Patient unwilling to participate in diabetes self-management or share pump management decisions with trained providers
Lack of pump supplies or mechanical pump malfunction
Health care team decisions are for the health and safety of patient.

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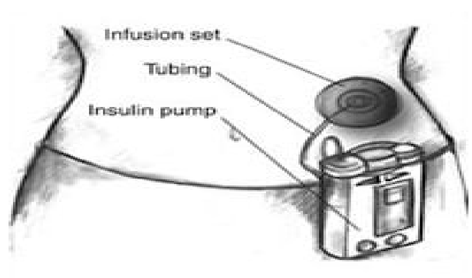
Pump variables to consider for patients 11

- How much insulin does it hold?
- CGM results displays on pump screen
- Reminder options
- Remote on glucose meter, device, apps, smart phones
- Ease of data download and readability
- How does it look, feel, clip features
- Alarms and other options
- Patients' current lifestyles



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Patients' Choice 12

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Rapid Insulin for Pump Therapy 13

Rapid acting insulin is used in the pump:
Novolog, Humalog, Apidra, Fiasp and Lyumjev

-Humalog u200, U500 regular insulin (off-label use)

- Improved before and after meal glucose
- Improved overnight glucose
- Introduction of Fiasp and Lyumjev-provides opportunity to improve performance with faster onset and offset of insulin action

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Patients' Choice/issues 14

What features should an insulin pump have?
1.the highest dosage, also called a bolus, and if this is enough for a person's needs.
2.how much insulin the pump holds.
3.battery life and type.
4.compatibility of the infusion set, or needle and tubing.

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Changing Times:

- First closed-loop insulin delivery system was developed by Arnold Kadish in the early 1960s. -12
- Comprised of autoanalyzer for CGM via IV catheter and 2 intravenous syringe pumps containing insulin and either glucose or glucagon. -12
- Both pumps were shut off when BS levels were withing a defined target range -12
- BS dropped below the threshold the glucose or glucagon pump was activated. -12
- Kadish published the results from the first successful volunteer in 1963.-12


The first insulin pump prototype was developed by Dr. Arnold Kadish in 1963. It never made it to market because of its impractical size.

Reference 12

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Currently Available AID

Current systems are called "hybrid" closed-loop (HCL) systems as they require entry of carbohydrates consumed, and adjustments for exercise must be announced.

US
- Medtronic 770g with Automode
- Tandem T:slim x 2 with Control IQ
- Omnipod 5
- DIY system-

- **Outside US**
- CamAps FX
- Dialoop
- Medtronic 780



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Settings Adjustment Consideration:

	Medtronic 770g	T:Slim x 2 Control IQ	Omnipod 5
Modifiable Settings:	IOB I: Carb Ratio	Basal rates Correction factor I:Carb Ratios	I:Carb Ratios Correction factor Target Glucose DIA
Specialty Modes	Temp Target:150 mg/dl	Exercise Mode: Targets BS of 140-160. Sleep Mode: Target 110-120 mg/dl without correction bolus	Exercise Feature: Targets glucose 150mg/dl and decreases insulin delivery
Algorithm Consideration	Machine is learning and uses TDI (past 6 days) for calculation	Based on basal rates/correction factor + TDI over past 6 days	Machine learning adaptively occurs with each pod change

Coby EC, Berget C, Messer LH, Forlenza GP. Review of the Omnipod 5 Automated Glucose Control System Powered by Horizon for the treatment of Type 1 diabetes. Ther Deliv. 2020; 11 (8):507-519

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The new MiniMed 770g system automatically adjusts insulin levels and takes on more of the tasks of managing diabetes and continuously adapts to insulin needs based off real-time data and personal trends.

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Medtronic 670/770g

Targets glucose control by adjustment of basal rate.

- Basal rate calculated and adjusted every 5 minutes in response to CGM glucose trend and calculated insulin sensitivity.
- Insulin sensitivity is based on total daily insulin (TDI) over the past 6 days of data (calculated at 0000)
- Takes into consideration insulin on board (IOB) based on modifiable duration of insulin action.

Non-Modifiable settings for automation:

- Target 120 mg/dl (temp target of 150 mg/dl")
- Basal Rates
- Insulin sensitivity factor

Modifiable settings for automation:

- Duration of insulin action: Longer=smaller bolus because duration is longer, Shorter=bigger bolus because duration is shorter.
- Carbohydrate ratio (Does not impact algorithm outside of the total daily insulin
- Manual Correction bolus targets 150 mg/dl and algorithm then targets 120 mg/dl with basal adjustment
- Sensitivity factor for correction dose based on calculated ISF, not programmed ISF

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Medtronic 670g/770g

- **Safe Basal: Minimum basal insulin delivery determined from the insulin dosage in Auto Mode. If no action is taken in 90 minutes, exits to manual mode.**
  - **Missing BG, missing calibration, no SG signal received, minimum delivery quantity for >2 hours, max delivery quantity for >4 hours, BG and SG > 35% difference.**
- **Auto Mode Exits to Manual Mode:**
  - **SG >250mg/dl for >3 hours or >300 mg/dl for >1 hour, "Insulin flow blocked" alert**
- **Predicted Low Glucose Suspend**
  - **Suspends basal rate when in manual mode and paired with sensor and hypoglycemia is predicted**
- **Temp Target: set manually by patient to target 150mg/dl**
- **Requires (at minimum) BID BG calibrations**

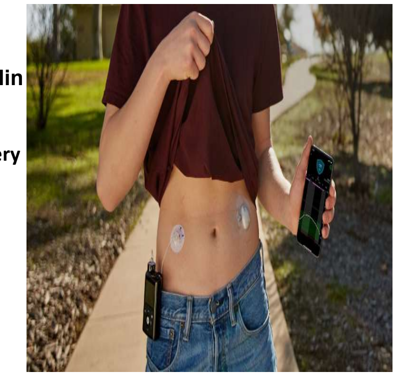

Photo credit: https://www.medtronicdiabetes.com.au/products/minimed-770g

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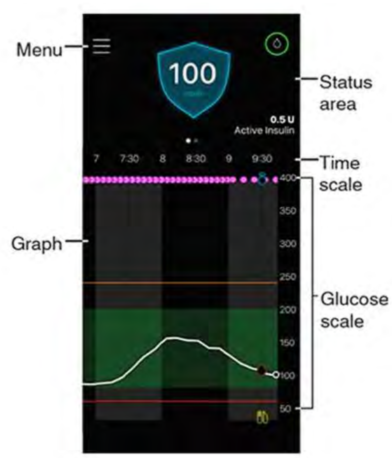
Medtronic 770g Mobile App

- Display may vary depending compatible mobile device and pump model.
- If Minimed mobile app hasn't been continuously running in the background, takes a few minutes for data to show up on app.
- Time in range graph appears by swiping left in the Status area.
- All notifications from the pump appear on the home screen.
- Alarm-red, alert-yellow and message-Blue
- Automatically uploads to carelink and sends notifications to family members.



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Medtronic Reports:

-Case Scenario: 22-year-old male with Type 1 Diabetes (2020)-complicated history- seizure disorder, HTN, HLD, on dialysis, cerebellar stroke and hypothyroidism.
-Went from insulin shots to insulin pump.
-A1C went from 8.2 to 6.6.

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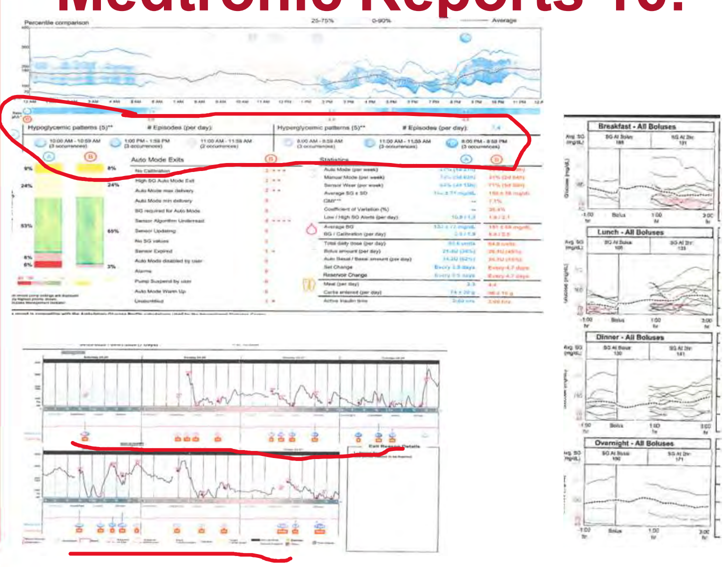
Medtronic Reports 16:



-Case Scenario:67 year old man with Type 1 diabetes for 20+ years.
-Complications: retinopathy. Eats low carb meals/likes tight control
-Pt had reached out regarding severe low BS that he was having and thought he was in automode.
-next visit was in automode >90% of time

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CONTROL IQ	SLEEP ACTIVITY	EXERCISE ACTIVITY
180	-	180
160	120	160
112.5-160	112.5-120	140-160
112.5	112.5	140
70	70	80

TANDEM DIABETES CARE

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Tandem T:Slim x 2 With Control IQ

- Targets glucose control through automated basal rate adjustments and automated correction bolus.
  - Automated correction bolus once an hour for glucose over >180 mg/dl
  - 60% of total correction bolus calculated by combination of pre-entered settings and TDI.

Non-modifiable Settings for Automation:
- Pre-set targets 110 mg/dl (112.5-160 mg/dl)
- Insulin on Board (IOB)

Modifiable Settings for Automation:
- Insulin to Carb Ratios-I:C ratios
- Basal rates
- Correction factor

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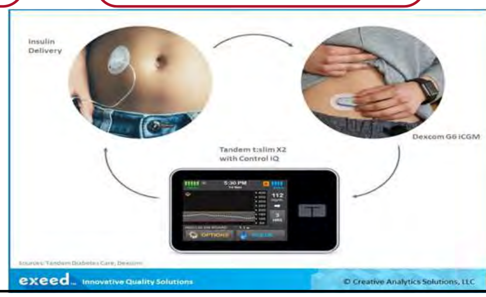
Tandem T:Slim x 2 Control IQ Features:

- Exercise: targets glucose of 140-160mg/dl with basal adjustment. Will deliver correction bolus (for glucose >160mg/dl basal adjustment, >180 mg/dl correction bolus.
- Sleep: target glucose of 110-120 mg/dl with basal adjustment only. Does not automatically deliver correction bolus.
- If no CGM data for >20 minutes. Exits to pre-programmed settings.



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Tandem New Features for Versions 6.6/7.6. with Mobile Bolus

- High Alert Adjustments: Adjustment to the Control IQ technology high alert behavior, now annunciate a maximum of once every 2 hours as long as the same high alert state remains.
- Switching Between Activities: If exercise activity is manually turned off during a programmed Sleep schedule time frame, the sleep activity will not start automatically.
- Additional Bolus Reminder: An additional bolus reminder will appear when Control-IQ technology is turned on and a fold bolus size greater than 25 units is calculated. The reminder will appear to allow for the additional remaining bolus to be delivered.

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Extended Bolus with CIQ 17:

- Allows you to deliver part of the bolus now and part of the bolus slowly over a period of up to 2 hours when in Control IQ (up to 8 hours if Control-IQ technology is turned off).
- This can be helpful for high-fat meals such as pizza, pasta, chinese food, grazing, coffee or if you have gastroparesis (delayed stomach emptying).
- When extending a bolus, any correction bolus amount will always be given in the DELIVER NOW portion.
- Important for patients to learn how to use this feature as well as you, as healthcare providers, as to how to properly use this feature for best outcome for the patient.
- Provide recommendations on the split between now and later and the duration for the later portion.-adustments will need to be made

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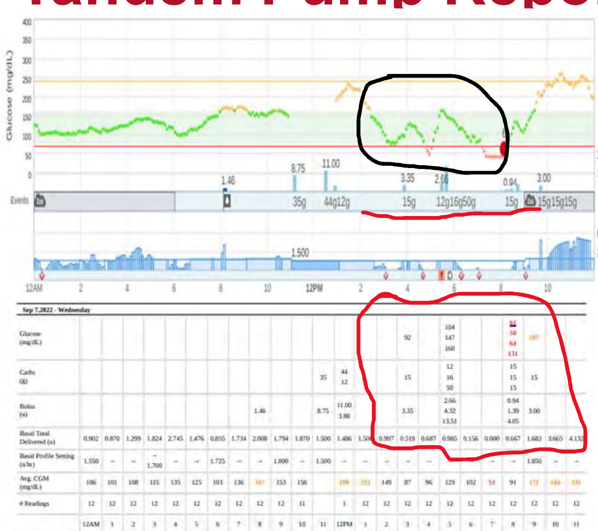
Tandem Pump Reports



Case Scenario: 38 year old female with Type 1 Diabetes for 20+ years. Started eating healthier and working out on Peleton Bike. Pt had gone on Peleton Bike for 30 minutes and then went to Amigos with family. Due to the large, high fat meal-Pt had taken more insulin to cover the meal. She did not do the extended bolus so prior to the food digesting her BS dropped from the large bolus and exercise. Pt then over treated the low BS and then continue to bolus to bring her BS down and crashed again.

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Tandem Pump Reports

Apr 7,2022 - Thursday																								
Glucose (mg/dL)								130			169		140 143			205						128		
Carbs (g)								46			22		42 10			38						38		
Bolus (u)								5.75		0.37	2.75		4.75 1.11		0.17	0.63 4.36						3.59	0.21	
Basal Total Delivered (u)	2.189	2.348	1.172	1.655	1.229	1.320	2.317	1.277	1.300	1.418	1.199	1.300	0.900	→	1.466	1.175	0.900	0.965	0.168	0.447	1.017	1.000	1.403	2.610
Basal Profile Setting (u/hr)	→	→	→	1.100	→	→	1.300	→	→	→	→	→	0.900	→	→	→	→	1.050	→	→	1.000	→	→	→
Avg. CGM (mg/dL)	222	197	162	143	133	123	147	137	183	184	155	149	144	180	209	212	218	158	94	88	125	140	194	224
# Readings	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12

-Case Scenario: 43 year old male with type 1 diabetes, complicated by gastorparesis, s/p pacer and NPDR

-He had reached out to the office regarding issues with high and low BS readings.

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OMNIPOD 5

Targets glucose control through an adaptive basal rate: determined based on historical insulin delivery (including TDI based on previous pod wears and weighted to most recent pod data).

- **First Pod with a New Controller//smartphone: Automated mode will be initiated based on pre-programmed basal rate, after 1st pod change will be based on the actual total daily insulin (adaptive basal rate).**
- **Insulin delivery is updated at every pod change.**

INSULIN MANAGEMENT SYSTEM

41327-ENG AW R1 11/18

omnipod®

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Omnipod 5

<u>Non-Modifiable settings for automation:</u>

- Basal rates

<u>Modifiable settings for automation:</u>

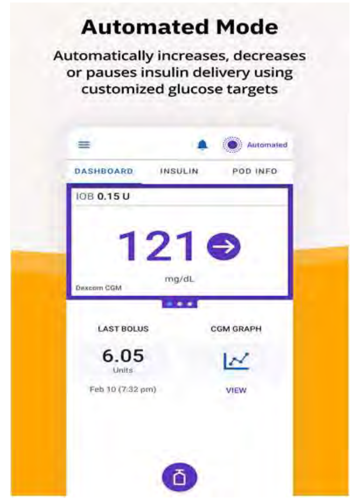
- Target Glucose:110, 120, 130, 140 and 150 mg/dl
- I:C ratios (for meal boluses)
- Correction factor (for high glucose correction boluses)
- Active insulin time (for user-given correction boluses only, not for automated insulin delivery

<u>Clinician pointers:</u>

Focus on behaviors-giving all boluses, wearing cgm

Make system more aggressive, consider lowering the target and intensity the ICR to increase the total daily insulin (which drives the automation calculation.

Pantherprogram.org.



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Omnipod 5 18

<u>Limited Mode:</u> **Entered if the Pod is not receiving CGM values for >20 minutes**	**Never gives more than the basal program would give in manual mode** **After 1 hour with CGM values, system alarms to alert user**
Activity Feature: Reduces automated insulin delivery and targets glucose 150 mg/dl	**Can be set for a duration of 1-24 hours, in increments of 1 hour**
Re-initiation restarts: system reverts to pre-programmed settings	**New controller/smart phone started** **After 30 days of gap in use**

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Omnipod 5 reports

-Case Scenario: 70 year old woman with Type 2 diabetes. Had been on the v-go and was switched to Omnipod Dash due to needing different basal rates throughout the day.

-Top diagram is her BS reports when on the Dash.

-Bottom graphs on the first week of the patient being on the Omnipod 5.

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Omnipod 5 reports

-Case Scenario:71 year old man with type 1 diabetes. Was on shots prior to starting insulin pump.

-1 weeks after pump start-Time in range increased from 69-86%.

-hypo events decreased from 6% to 3%.

-2 weeks post pump-TIR is 93%.

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DIY LOOP or open APS

- NOT FDA approved
- May require radio transmitter (Riley link) for communication between older pump models. (10)
- Offers more customization and aggressive targets than commercially HCL-set personal parameters.
- Frequent updates, to system algorithm and features (10)
- There are presently three systems—OpenAPS, AndroidAPS and Loop (10).
- "I've seen firsthand how these (DIY) systems can improve glucose control, reduce rates of hypoglycemia and make significant improvements in quality of life… it's really no wonder that patients are seeking out this solution. It is time to be aware of it, and it is time to be prepared." Jeremy Pettus, MD Endocrinologist and Associate Professor of Medicine, UCSD School of Medicine Endocrine Today, Vol 16, No 11, November 2018

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Patient tricks-20

- NOT FDA approved
- Several different iterations of algorithms available
- May require radio transmitter (Riley link) for communication between older pump models. (10)
- Offers more customization and aggressive targets than commercially HCL-set personal parameters.
- Frequent updates, to system algorithum/features (10)
- Was limited to tech savvy patients and families, but as popularity grows wider adoption is occurring (10)
- There are presently three systems—OpenAPS, AndroidAPS and Loop (10).

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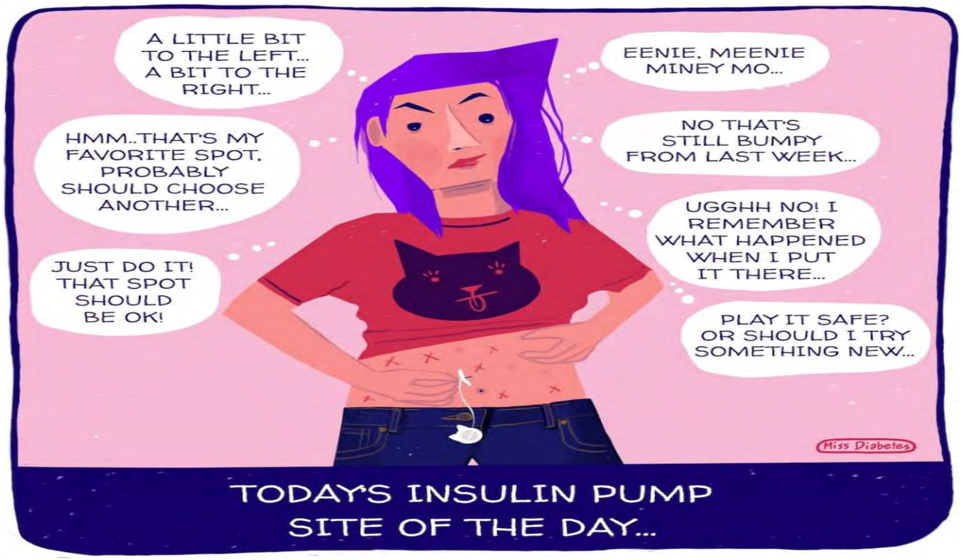

https://missdiabetes.com/life-with-diabetes-comics/

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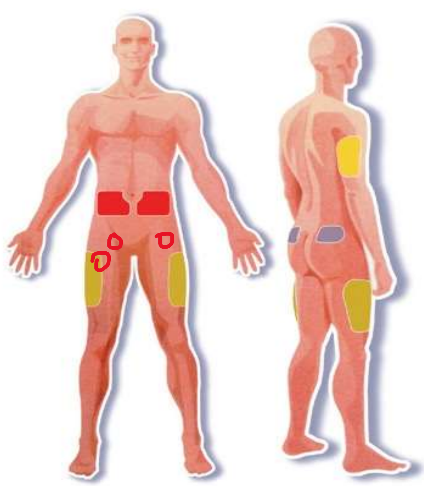
Sites should be rotated every 2-3 days



- **Locations:**
  - Outer Arm
  - Abdomen
  - Hip area
  - Thigh

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Continued Patient Assessment Criteria 21

- Avoid using CGMs for management decisions in the following settings
  - Severe hypoglycemia or hyperglycemia (BG <40 or >500).
  - Diabetic ketoacidosis until glucose is in the new CGM measurement range, and then for adjunctive use
  - Patients with rapidly changing glucose levels and fluid/electrolyte shifts.
  - Patients with skin injections near the sensor site or placing sensors in areas with significant edema.
  - Patients treated with vasoactive agents or poor tissue perfusion.
  - These are vital things that the patients need to be aware of.

Image-"What Someone is Probably Thinking When They See My Insulin Pump." 2018. Meme. Accessed November 3, 2020. https://me.me/i/what-someone-is-probably-thinking-when-they-see-my-insulin-22122611.

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Accuracy Requirements for iCGM 22

FDA iCGM Class II	Glucose Range	Criterion **	Criterion **
	<70 mg/dl	+/- 15 mg/dl	85%
		+/- 40mg/dl	98%
	70-180 mg/dl	+/- 15%	70%
		+/- 40%	99%
	>180	+/- 15%	80%
		+/- 40%	99%
	All Glucose	+/- 20%	87%
	<70mg/dl >180 mg/dl	No ref vaules >180 No ref values <70	

U.S. Food and Drug Administration-last updated 3/29/22

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CGM Accuracy 23

- Accuracy is often typically assessed by measuring difference of CGM glucose versus comparator glucose value (lab, POC BG meter)
- Comparator glucose measuring device has degree of error (particularly fingerstick BG)-5,6
- Measuring different fluids: interstitial fluid vs blood (e.g. capillary blood)
- Known lag time between interstitial and blood glucose averages –9 minutes and varies based on the glucose levels, rate of change, sensor wear time and need for calibration, as well as differences between individuals and sensors-5,7, 8

- References on slide 3

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From the Patient's Side:

https://type1diabetesmemes.tumblr.com/image/21066151683

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Life Situations with Closed-Loop Systems 24:

- Accuracy is often typically assessed by measuring difference of CGM glucose versus comparator glucose value (lab, POC BG meter)
- Comparator glucose measuring device has degree of error (particularly fingerstick BG)-5,6
- Measuring different fluids: interstitial fluid vs blood (e.g. capillary blood)
- Known lag time between interstitial and blood glucose averages –9 minutes and varies based on the glucose levels, rate of change, sensor wear time and need for calibration, as well as differences between individuals and sensors-5,7, 8

- References on slide 3

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Life 25

Some first-generation hybrid closed-loop systems use a relatively high glucose target (6.7 mmol/l) and lack flexibility to adjust the target to suit the needs of the user. This makes the system unsuitable for those aiming for tighter glycaemic control, including pregnant women.

Postprandial glucose excursions remain a challenge for closed-loop systems due to inherent delays in subcutaneous insulin absorption. User interaction with accurate carbohydrate counting and pre-meal bolusing is required for optimal glycaemic control. Attempts to reduce user burden with simplified meal boluses or fully closed-loop systems have resulted in compromised glycaemic control [29, 30].

Managing physical activity can be challenging primarily due to increased hypoglycaemia risk and altered insulin sensitivity. Even with closed-loop glucose-responsive insulin delivery, users usually need to plan for exercise, announcing exercise to the algorithm in advance, and may still require carbohydrate intake to prevent hypoglycaemia [31, 32]. Carbohydrate loading before exercise can be problematic with glucose-responsive insulin delivery, often resulting in hypoglycaemia during exercise.

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Further Improvements that could help HCL systems 26:

- Better interoperability between different pumps and cgms.
- Insulin that acts faster and clears the system faster
- Implantable CGM technology that's integrated with insulin pump
- Easier general usability and simplifying the overall work of using a closed loop system.
- Making closed-loop systems affordable and accessible to everyone who is interested.

Reference 13

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Insulin Pumps, next steps 27:

- If more education is needed, then patient is set up for additional education.
- Once the education is completed, the educator will determine if patient is ready to move forward with the insulin pump.
- If there are questions regarding the patient's safety,
  - Notify referring provider.
  - Additional education scheduled.
  - Saline trial.
    - If unable to safely manage, deemed not appropriate to move forward.
- Triangle approach, patient, provider and educator should be on the same page with next steps and determination if patient is appropriate for insulin pump usage.

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Summary 28

- Must be followed by clinicians experienced in diabetes and AID
- Assess appropriateness of the patient in current clinical condition
- Assess AID algorithm for appropriateness in current clinical condition
- Consider use of exercise or alternative glucose targets
- Consider modifiable setting changes to meet clinical condition
- Exit to manual mode if any concern for automated delivery
- Support ongoing research for appropriate use (or initiation??) of AID in the outpatient setting.
- There is still scope for further improvements to optimize postprandial glucose control, exercise management and usability before this technology can be said to truly reduce the burden of diabetes.
- Widespread adoption and reimbursement of closed loop systems will be critical to ensuring equitable access to this technology.

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Questions?

Feel free to contact me at:
gmcvey@nebraskamed.com

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