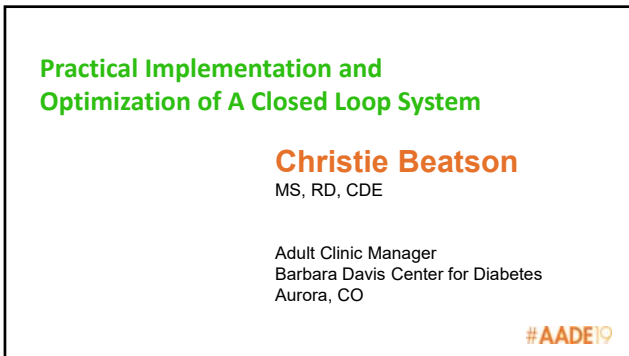
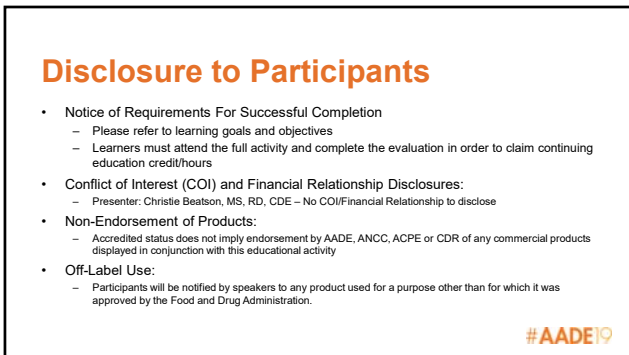


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Objectives

- Name the features of a Hybrid Closed Loop (HCL) System
- Set Patient Expectations for HCL use
- Facilitate continued patient success using HCL

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What is a Hybrid Closed Loop (HCL) System

A system where the insulin pump delivers insulin based on sensor readings and an algorithm



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SAP VS HCL

Sensor Augmented Pump (SAP):

- Sensor data is read on the pump
- Pump may make some insulin shut off decisions based on sensor data
 - Insulin is suspended for set amount of time once low threshold is reached
- Predictive low glucose suspend
 - Insulin is suspended 30 minutes before sensor glucose is predicted to drop below 80 mg/dL and resumes once glucose has risen above 80 mg/dL (1/2 HCL)



Hybrid Closed Loop (HCL):

- Medtronic 670G - Only FDA Approved HCL System
- Approved Sept 2016 (Children 7-13 June 2018)
Pump makes insulin delivery decisions based on sensor glucose and algorithm (able to give more insulin and suspend insulin based on sensor glucose)



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Pump evolution 1970's - Future

The diagram shows five stages of insulin pump evolution, represented by figures that look like they are evolving from an ape to a modern human. Below each figure is a label for the technology:

- Insulin pump
- Sensor Augmented Pump
- Suspend on or before low
- Partial automation 1 or 2 hormone
- Full Automation/ Personalization Artificial Intelligence

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A Closer Look at Medtronic 670G

Auto Mode (Closed Loop)

- 670G terminology for hybrid closed-loop mode
- system replaces programmed basal rates with auto-basal delivered every 5 minutes based on sensor glucose level
- Algorithm calculates auto-basal from Total Daily Dose over the past 2-6 days
- Requires ≥ 8 units and ≤ 250 units per day
- Target 120 mg/dL

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Auto Mode Continued

- Patient must bolus for all carbs consumed (Hybrid Closed Loop)
 - Bolus calculator accepts carbs and BG only
 - Bolus is calculated from programmed carb ratio and active insulin time
 - Only 2 modifiable settings in auto-mode
 - Cannot override bolus recommendation
- Correction bolus is offered if entered BG >150 mg/dL
 - Target of 150 mg/dL for corrections
 - Sensitivity factor calculated by system using 1500 rule

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Patient Expectations



Set Realistic Initial EXPECTATIONS
1-2 month learning curve:

- More alerts
- Less than optimal BG control while optimizing dose settings

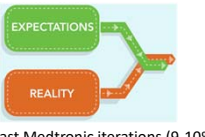
Work load:

- 3-4 calibrations/day
- Entering and exiting Auto Mode (potential additional BG requests)
- Still need to bolus for meals
- **Need for close Follow Up (Remote or Face to Face)**

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Patient Expectations



REALISTIC EXPECTATIONS

Accuracy

- Guardian™ Sensor 3 more accurate than past Medtronic iterations (9-10% MARD)


Glucose control

- In clinical trials, HbA1c decreased 0.5% in 3 months
- A1c may go up if patient has significant hypoglycemia
- Most noticeable improvement overnight/fasting in clinical trials
- Increased time in range 70-180 mg/dL and less hypoglycemia
- Will still have some hyperglycemia and some hypoglycemia

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What patient might be more successful on HCL?



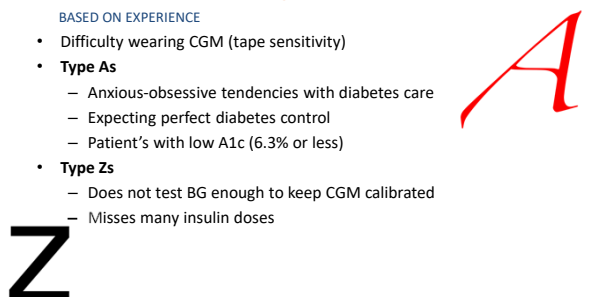
- Comfortable wearing pump and sensor
- Test BG ~4 times/day
- Gives most meal boluses
- Not obsessive/controlling of diabetes
- Understanding the system will aid in diabetes care but will not control diabetes for them
- Willing to give control over to a system
- Willing to give it 1-2 months to optimize settings

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Who is not ideal? Type As and Zs

BASED ON EXPERIENCE

- Difficulty wearing CGM (tape sensitivity)
- **Type As**
 - Anxious-obsessive tendencies with diabetes care
 - Expecting perfect diabetes control
 - Patient's with low A1c (6.3% or less)
- **Type Zs**
 - Does not test BG enough to keep CGM calibrated
 - Misses many insulin doses



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Keys to Success: Three C's

- Carbs
- Calibrations
- Corrections

Goal: To Stay in Auto Mode as much as possible
Increased Time In Auto Mode = Increased Time In Range

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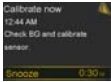
Carbohydrates 

- Patients should bolus for all carbs consumed, patients may need to bolus for coffee/caffeine
- Accurate carb counting helps
- Pre-bolusing helps
- Most patients need to strengthen carb ratio by ~20% (15→12, 12→10), however can be too aggressive and cause auto-basal to shut down too long after meals
- Consuming large carb meals can make staying in Auto Mode more difficult
- Avoid entering carbs not actually consumed to get corrections, over estimating carbs or entering more carbs than consumed can cause auto-basal shut off and rebound hyperglycemia

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Calibrations

Calibrations = Sensor accuracy




- System requires at least 1 calibration every 12 hours, may request additional calibrations
- Good practice to calibrate before bed to avoid calibration request while sleeping
- Use good finger stick technique for calibrations (no alternate site, wash hands)
- No need to over calibrate, no more than 2-3 per day
- If repeated calibration requests, **STOP** and try again 30 min -1 hour later
- Best to calibrate when glucose is not changing rapidly (no or only 1 arrow)
- If not a good time to calibrate, set snooze and revisit later

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Corrections

- Corrections are helpful and often necessary to stay in Auto Mode
- Most patients need a more aggressive Active Insulin Time (usually 2.5 – 3 hours)
- Correcting after dinner and/or before bed can avoid unnecessary auto-mode exits
- BG must be entered for the system to offer a correction
- Over time, corrections add to the TDD and increase auto-basal delivery if needed
- Avoid over correcting lows which can cause a rebound hyperglycemia
- Look at sensor graph, if no pink dots then treat cautiously (5 grams of carbs)



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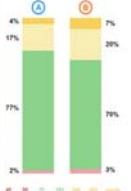
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Increased Time in Auto Mode= Increased Time Range

New metric:
Analyzes time spent within glucose range:

- ≤50 mg/dL
- 51-70 mg/dL
- 71-180 mg/dL
- 181-250 mg/dL
- 251-400 mg/dL

GOAL: Increase the percentage of time spent in target (71-180 mg/dL)



Time	Target (71-180 mg/dL)	Other Ranges
Before	77%	23%
After	80%	20%

Goal: Auto Mode
80% of the time


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Time In Range – What is the goal?

Time in range	FBATC (%)
0%	12.1
10%	11.4
20%	10.8
30%	9.8
40%	9.0
50%	8.3
60%	7.3
70%	6.7
80%	5.9
90%	5.1

- Must be individualized for each patient with goal to improve over time
- 0% Time ≤ 50
- 1-5% 51-70
- 60-70% 71-180




Vigersky, OTT, Feb 2019

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Real World Frustrations and How can you help?

- Too many BG requests
- Too many calibration requests
- Auto-Mode exits
- Make sure patient has most updated version of transmitter (2.2A)
- Try to calibrate only 2-3 times per day, before breakfast, lunch or dinner, and bedtime
- Determine reason for Auto-Mode exit (high sensor BG, safe basal time-out, missed calibrations)
- Sometimes it's patient behavior and not settings that need to change



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What causes Auto-mode Exits?

<p>Most common reasons:</p> <ul style="list-style-type: none"> • High SG: 300 mg/dL for 1 hour • High SG: 250 mg/dL for 3 hours • Missed calibration • Min (2.5 hr)/Max (4 hrs) delivery • Ignoring BG required alert → leading to safe basal time out 	<p>Potential Solution:</p> <ul style="list-style-type: none"> • Pre-Bolus for meal or check carb counting • Tighten carb ratio • Carb counting instruction • After meal correction if needed • Adjust Active Insulin time • Respond to BG required (not calibrations) to avoid safe basal time out
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Successful Implementation of HCL

- Help patients choose the best system
- Set patient expectations
- Training and follow up is the key to success
- New to pump and CGM patients may take 1-2 months to get into auto-mode

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New to Pump and CGM: 1-2 months

1. Initial Pump and CGM training (can do together if tech savvy patient).
2. Possibly 2 separate trainings, maybe CGM first to help in fine tuning manual mode settings.
3. Manual mode (programmed basal rate) for 2 weeks to 1 month depending on patient and follow up.
4. Follow up every few days to weekly to fine tune basal rates and bolus settings (Carelink).
5. Auto-mode training: face to face or remote?
6. Follow up: weekly by Carelink and 1 month clinic visit

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Pump upgrade: 1-2 weeks

- Pump and CGM training together
- Auto-mode training: face-to-face or remote
- Patient can turn on Auto-Mode 48 hr after pump start but we recommend 5-6 days later
- Remote follow after 1 week in Auto-Mode (Carelink) and in clinic follow up 1 month after starting auto-mode

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With Education and Support patients have great success on HCL



31 year old female
3/22/17 A1c 9.7%
Started on 670G in
Auto-Mode 5/27/2017
A1c 8/21/18 7.7%

Orange period B
pre-auto-mode
Blue- period A is 3
months after
starting Auto-Mode
8/11/17-8/24/17
