INSULIN PUMP MADE EASY

• COURSE 101



CONTENTS

- CASE; TYPE 2 DIABETES ON PUMP
- OLD WAY OF DOING PUMPS COMPLICATED RIGHT?
- NEW PUMPS AND TECHNOLOGY
- NEW NON PUMP TECHNOLOGY

Relationships with commercial interests:

Grants/Research support NOVONORDISK; SANOFI

Speaker's bureau/honoraria:DEXCOM; ANIMAS; MEDTRONIC;

ELI LILLY NOVORDISK; BI; SANOFI;

Consulting/Advisory Board:SAME AS ABOVE

Other/Patents

Presenter Disclosure

Plan:

Type 1.5 diabetes

Declined to see genetics to rule out Mody or monogenic diabetes

Blood pressure near target

LDL A1c at target

Recent hair loss TSH on the low side

To repeat labs with graves antibody

She is having nuclear scan

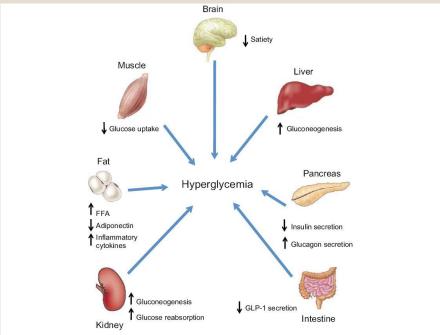


Figure I Multiorgan and tissue pathophysiology of type 2 diabetes.

Notes: Adapted with permission from DeFronzo RA. Banting Lecture. From the triumvirate to the ominous octet: a new paradigm for the treatment of type 2 diabetes mellitus. Diobetes. 2009;58:773–795.

Abbreviations: FFA, free fatty acids; GLP-1, glucagon-like peptide-1.

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Physical Exam:

Physical Exam
Looks well
bp on high side
Thyroid normal
cvs normal
resp clear
abd some lipohypertrophy
Feet 2 plus monofilament normal

Plan:



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Checks BG 4 times per day for the past ninety days.

Hypoglycemia: 83 percent in range

Less than 1 percent lows

Finds she has to eat at bedtime to prevent lows at nigh Prior cath; one small artery; no tx; just medical treatment She is overall feeling very well

No major lows

On insulin pump therapy

And SGLT2 inhibitor and GLP-1 agonist

She is aware of sick day rules

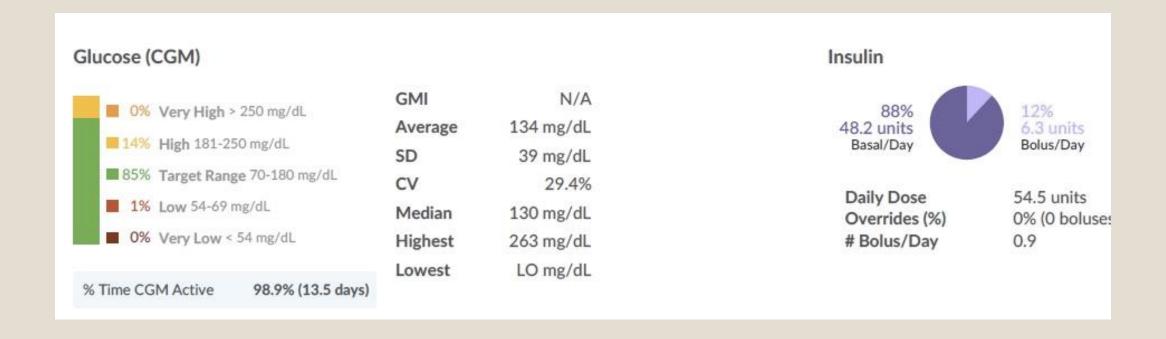
She was found to have a lung nodule that is being followed

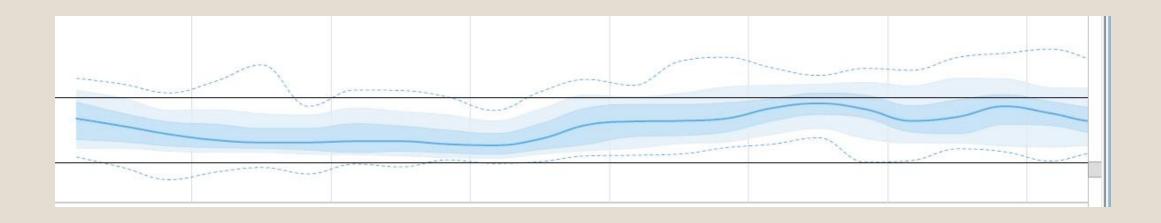
She goes for yearly eye exams

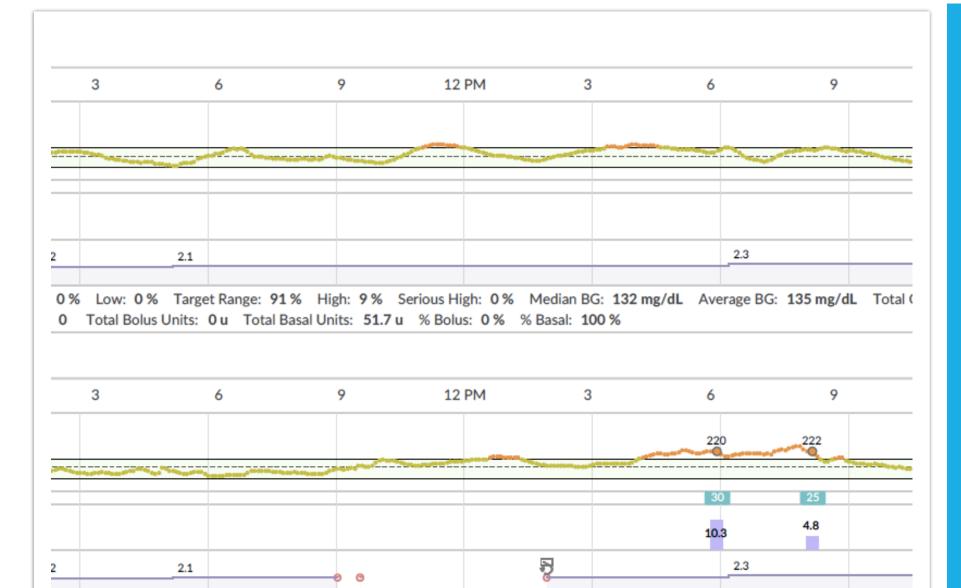
She is very happy with the current management

However feels she has to eat at night to prevent lows

TIME IN RANGE







0 % Low: 0 % Target Range: 78 % High: 22 % Serious High: 0 % Median BG: 138 mg/dL Average BG: 142 mg/dL ngs: 2 Total Carbs: 55 g # of Boluses: 2 Total Bolus Units: 15.1 u Total Basal Units: 41 u % Bolus: 27 % % Basal: 73 %

MOSTLY RUNS ON BOLUS

- TYPE 2 DIABETES ON ORALS AND GLP1 AGONIST
- INSULIN PUMP THERAPY IS A REASONABLE OPTION

CONTENTS

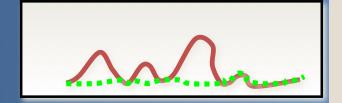
- CASE; TYPE 2 DIABETES ON PUMP
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Similarity Between Insulin Pumps and a Normal Pancreas

Basal rates

- Continuous infusion of insulin 24/7 based on "individual" body needs
- Covers the body's non-food needs

Normal pancreas

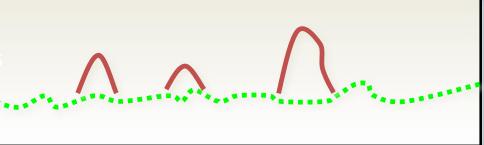


Bolus delivery

- Burst of insulin used to meet the requirements of food intake (based on CHO ratio)
- Can be used to correct high blood glucose readings

Covers the body's <u>food</u> and <u>correction needs</u>.

Pump Basal/Bolus



CHO: carbohydrate

THREE CONCEPTS TO KNOW

- BASAL RATE
- BOLUS AND CARB RATIO
- CORRECTION FACTORS

Pump Concepts: TDD and Basal

- Total daily dose (TDD) is the absolute total of insulin over 24 hours
- Basal insulin represents the 24/7 continuous infusion of rapid-acting insulin broken into increments (usually by the hour, but can be by 30 minute increments for some pumps).

Establishing the Basal Rate...

75-80 % of TDD previously taken with 50% as basal, then divided up over 24 h (TDD $\times 0.8 \times 0.5 =$ X/24 h) OR

0.75 X weight in kg = TDD 40-50 % of TDD = initial basal amount divided by 24 for approximate per hour dose...

Basal rates	Units/ hour
24 – 04	0.6
04 - 08	1.0
08 – 12	0.75
12 – 18	0.75
18 – 24	0.75

Present TDD = 45 u 80% of TDD = 36 u (New Pump evening to facilitate TDD) 50 % of 36 u = 18 u 18 u/24 = 0.75 u/hr

To facilitate future adjustments:

- ः चित्रस्मि। अस्ति विश्वासिक्या विश्या विश्वासिक्या विष्य morning, afternoon and adjustments
- May set up adjustment for dawn phenomenon

TDD: total daily dose; RA: rapid-acting insulin analogue

Establish CHO Ratio Settings

- Use of the pump computer to calculate the meal dose will help optimize care and often represents weakest link
- Education on CHO counting
 - Nutritional review with dietician comfortable with teaching CHO counting¹
 - Use of additional information and on-line sources (e.g., CalorieKing)
 - Consideration of fat and protein contents of meal²
- Most people do best using CHO counting but for some, it is overwhelming – KISS (Keep it Simple Stupid) concept use may help...
- Examples of 15-g portion sizes:
 - 1 starch portion (e.g., 1 slice of bread)
 - 1 fruit/vegetable portion (e.g., an apple)
 - 1 cup of milk or yogurt

1. CDA. Basic Carbohydrate Counting for Diabetes Management.

Available at: http://www.diabetes.com/los-professionals/resources/nutrition/basic-carb-counting

CHO: carbohydrate

2. Bao J, et al. Diabetes Care 2011;34:2146-51.

Pump Concepts: Bolus

- Bolus insulin dose(s)
- 1. Meal bolus(es) are based on an individual's insulin-tocarbohydrate ratio (ICR)
- 1 unit of insulin for X grams of CHO intake
- e.g., ICR 8 and meal 40 g ... means for 40 g/8 g = 5 u for meal
- 2. <u>Correction dose(s)</u> are based on the insulin sensitivity factor (ISF)
- 1 unit of insulin drops the BG by X mmols.
- BG target range entered

e.g.,

► Current BG: 14.0 mmol/L; Goal BG: 6.0 mmol/L

ightharpoonup Current BG — Goal BG = 14 — 6 = 8 mmol/ L (too high)

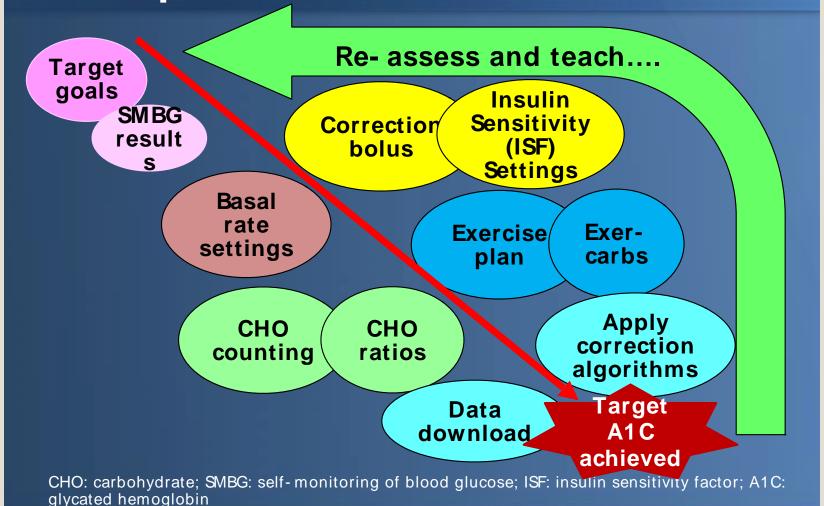
▶ ISF = 1 unit per 2 mmol/ L glucose- lowering expected

 \triangleright 8 / 2 (ISF) = 4 u to correct

CHO: carbohydrate;

BG: blood glucased from Walsh J, Roberts R. Pumping Insulin: Everything You Need to Know for Success with an Insulin Pump. 2006.

Components of Pump Adjustment to Improve Glucose Control



Setting Insulin Sensitivity Factor (ISF) or Correction Factor...

Formula calculation:

90 - 100* mmol/TDD

e.g., **90/36 = 2.5 mmol/L**

→1 u will likely lower glucose by 2.5 mmol/L

OR

Pragmatic assessment:

Ask patient how many units extra they would take to correct a glucose value, e.g., from 10 mmol/L to 6 mmol/L If 1 u = ISF = 1 u/4 mmol/L; If 2 u = ISF = 1 u/2 mmol/L,

etc. Can adjust for time of day

(perhaps more at breakfast and slightly less in evenings)

e.g., 1 u/1.5 mmol/L from 06-10 h;

1 u/2 mmol/L from 10-21 h;

1 u/3 mmol/L from 21-06 h.

Adapted from: Bode, BW. Pumping Protocol: A Guide to Insulin Pump Therapy Initiation. Atlanta, GA: Atlanta Diabetes Associates, 2008: p. 3.

^{*} In Canada, the 100 rule is most commonly used to determine the ISF. However, some use 90 or 110 based on patient sensitivity/resistance.

"Insulin on Board" (IOB) or "Active Insulin" Concept

- After the subcutaneous injection Example Bolus of insulin by the pump, the insulin is absorbed slowly and degraded. For rapid-acting insulin, this usually provides a duration of activity of about 4 hours.
- The "duration of insulin action" is thus routinely set at 4 hours.
- The pump will automatically include any remaining insulin from a previous bolus within the Adjustment for IOB: last 4 hours in the next bolus

Calculation

Estimated lunch CHO = 50 g CHO Ratio of 1 u/10 g

Bolus dose for CHO = 5 u

BG at 8.9 mmol/L ISF set at 1 u/2 mmol Target at 5-7 mmol/L Correction bolus (8.9 - 7/2) =1 u

Active insulin from 2 units correction bolus given 2 h ago $2h/4h = \frac{1}{2}$ of 2 units = 1 u

CHCarculations: blood glucose; ISF: insulin sensitivity factor

Bolus Calculator: Example 1

Example: BG = 12.5 mmol/ L and CHO intake = 50 g; correction

bolus of 2 units was made 2 hours before.

Pump INFO				
ICR:	14			
ISF:	2.5			
BG target:	6.0			
Active insulin:	4 h			

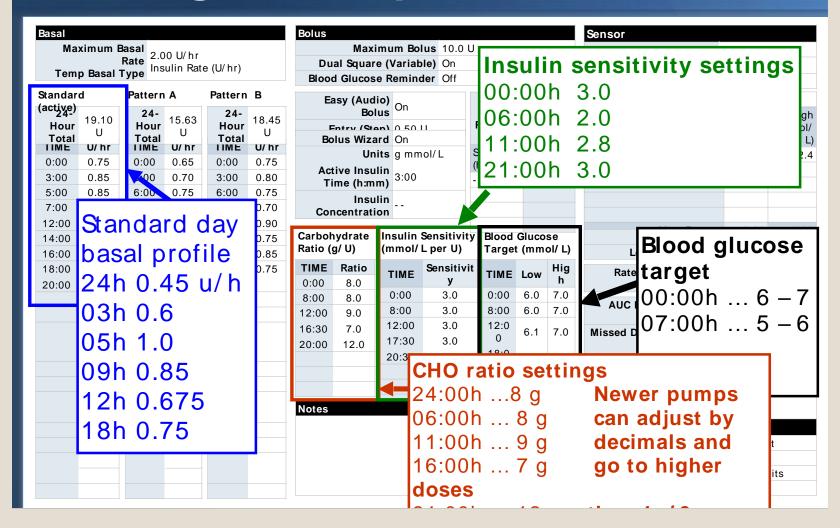
*NOTE: An assumption that half of the correction bolus of 2 units remains active since half of the 4 hours has passed (i.e., 1 unit of insulin remains active as IOB)

Total Bolus : 5.1 u (not 6.1 u)					
Food Intake:	50 g				
Meter BG:	12.5				
Insulin for food:	3.5				
Correction insulin:	2.6				
Adjustment for active Insulin:	1.0				

50 g ÷ 14 (CHO Ratio) 3.5 u (Food Bolus)		
12.5 mmol/L-6.0		
mmol/ L		
: 2 5 mm al/1 (ISE		
<u>÷ 2.5 mmol/ L (ISF</u>		
<u>- Sensitivity)</u>		
2.6 u (Constion)		
2.6 u (Concection)		
2.6 u (Correction) - 1.0 u (IOB - Active		
Insulin)*		
1.6 u (Adjusted		
Correction)		

ICR: insulin-to-carbohydrate ratio; ISF: insulin sensitivity factor; IOB: insulin on board; CHO: carbohydrate; BG: blood glucose

Settings: Example



Activity and "Exer- Carbs"

- An exer- carb is the relative number of carbohydrates which would need to be eaten to offset the exercise undertaken...
- The relative amounts are available in tables
- Can use their value to reduce from meal bolus taken prior to the exercise or recently after an exercise







Planning for Activities....

Encourage patients to set up a plan for a recurrent activity and fine tune it with them until it works...

Type of activity	Reduction Bolus (%) Basal (%)	Temporary basal defined in advance (yes/ no)	Time set for temporary basal	Effective control or adjust next time?
Light (gardening, walk, shopping)	~	~	~	~
Moderate (biking, golfing [no cart])	~	~	~	~
Energetic (basketball, jogging, swimming)	Reduced basal to 50% 30 min before run & during activity	Yes	Time of run & 30 min before	Went a bit low, try 50% decrease 1 hour prior to and during activity
Endurance (skating, cross- country skiing, hiking)	~	~	~	~

Rule of Thumb: Since it takes rapid insulin up to 1 hour to begin peaking, temporary basal for exercise needs to be set 1 hour prior to the activity to reduce the risk of hypoglycemia

Pump Setup

- Educate patient to competency, which will require more than one training session
- Determine TDD
- Set basal rates (generally ½ of TDD)
- Set bolus parameters
 - ICR: insulin/carbohydrate ratio (carbohydrate factor)
 - ISF: insulin sensitivity factor (correction factor)
 - Target glucose/active insulin time (varies between systems)
- Instruct the patient in pump features, troubleshooting
- Instruct the patient in use of apps, downloading devices, etc

REPEAT!

Troubleshooting

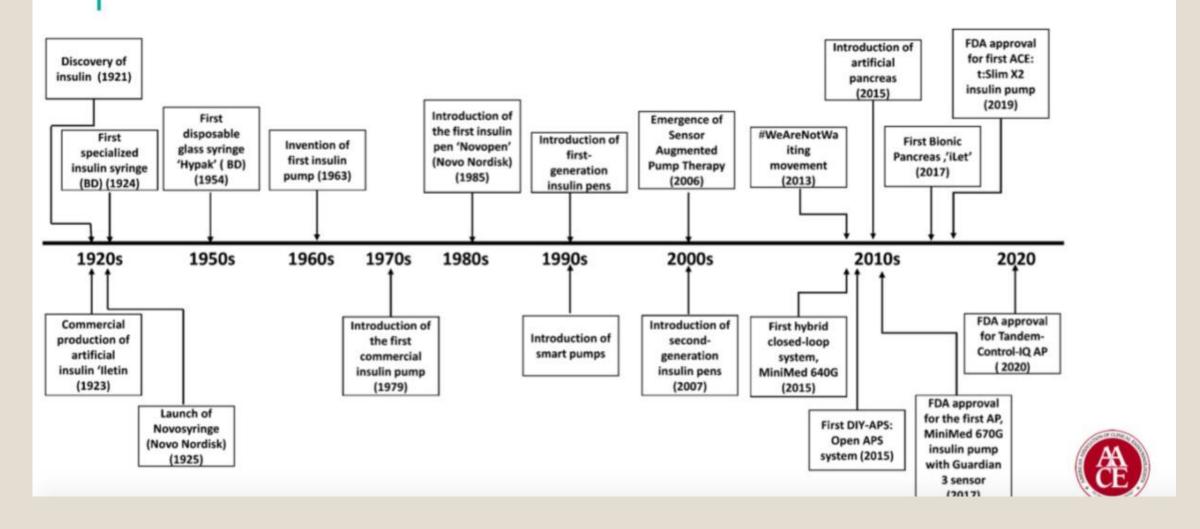
- Unexpected highs

 infusion set or site problem until proven otherwise; low reservoir, low battery, overheated, or cooled insulin are also causes
- "Third day effect" may be due to insulin exposure and degradation
- Illness and steroids may require temporary basal rate, manual mode
- Exercise
 individualize rate changes, nutrition
- Lows > replace CGM, check basal rate settings, downloads for errors, change carb ratio

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Diabetes Technology Timeline



MiniMed 780G HCL: Available in 2021?

- Guardian 3 CGM, algorithm changes
- 780G pump is Bluetooth connected
- Adjustable glucose target, down to ~100 mg/dL
- Automatic correction bolus doses, will correct for missed carbs, ↑ TIR to 80%+
- Bluetooth capability on the pump (will start with 770G model), communicates with smartphone
- CGM calibration required twice only on Day 1
- FDA approval for Guardian 3/Zeus nonadjunctive use is pending



Insulin Only, Bihormonal, Closed Loop



Components

- Dexcom G6
- iLet insulin pump
- Rapid acting insulin vs insulin plus glucagon
- HCL → CL, requires only body weight and meal announce
- Pivotal trial is underway

Tidepool Loop: A DIY Algorithm Submitted to FDA



Components

- Dexcom G6
- Omnipod or possibly Medtronic pump (future)
- Algorithm resides on a smartphone; goal is availability at the App Store

Tandem Insulin Pump: t:slim X2



Shows CGM trend line, glucose and direction arrow

- Bolus delivery: 1 unit in 20 seconds
- Extended bolus includes "Now" delivery for correction amount
- Insulin:carb ratios <1u:10g can be programmed in fractions, ie, 1u:5.5g
- Different insulin:carb ratios across the day
- Basal IQ incorporates PLGS with auto-shut off
- Control IQ is HCL program, adjusts the basal rate and does correction boluses
- Note that a prescription is needed for the algorithm

T:Connect Download Report, Control IQ







Slide credit: Janet B. McGill, MD; endocrine.org, diabeteseducator.org, clinicaloptions.com

Medtronic 670G and 770G systems

Automatic transmission of BG:



670G

If Contour Next Link 2.4 meter is linked, BG automatically transmits to pump

If Contour Next Link 2.4 meter is not linked, BG can be entered manually









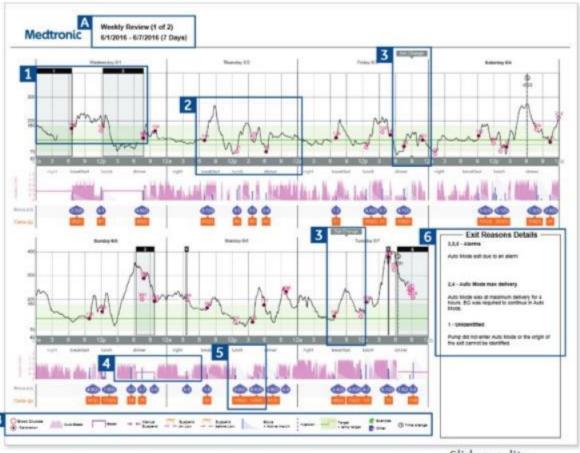


Slide credit:

Janet B. McGill, MD; endocrine.org, diabeteseducator.org, clinicaloptions.com

Medtronic CareLink Report



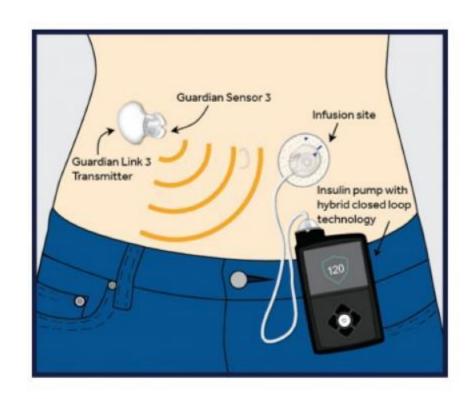


Slide credit:

Janet B. McGill, MD; endocrine.org, diabeteseducator.org, clinicaloptions.com

Medtronic 670G/770G systems

- Guardian 3 CGM; SmartGuard program
- Hybrid closed loop adjusts basal rates only;
 PLGS in manual mode (alarm + shutoff)
- Nighttime glucoses are flat
- Patients enter glucose and carbs for bolus dose calculation
- Set for average BG of 120 mg/dL (6.7 mmol/L); corrects to BG of 150 mg/dL
- Approved for ages 7+, minimum TDD >8 units
- Need to wear for 3+ days in manual mode prior to turning on auto mode
- Handles insulin doses 8-250 units
- PID algorithm is not equipped for illness/steroids



Patch Pumps

Qforma

Flexible Patch Pump



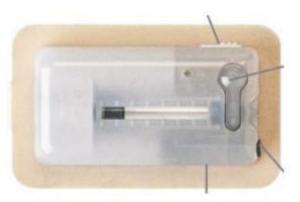


Simplicity

Bolus doses only, 2-unit increments; FDA approved, not launched

https://www.myceqursimplicity.com/launched https://www.accu-chek.co.uk/insulin-pumps/solo https://www.go-vgo.com/ FDA approved, launched in Europe





V-Go, disposable patch pump Basal rates of 20, 30, 40 units/day Bolus doses in 2-unit increments Mostly used in T2D



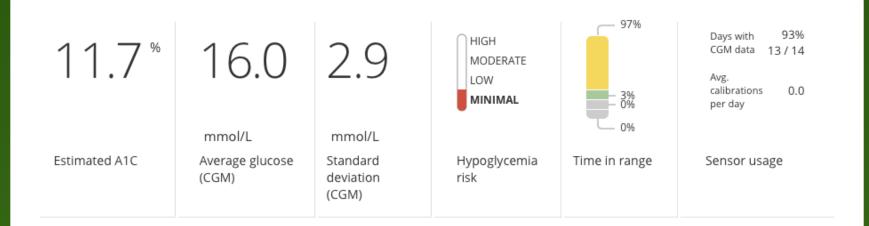
Slide credit: Janet B. McGill, MD; endocrine.org, diabeteseducator.org, clinicaloptions.com



BF; hyperfear

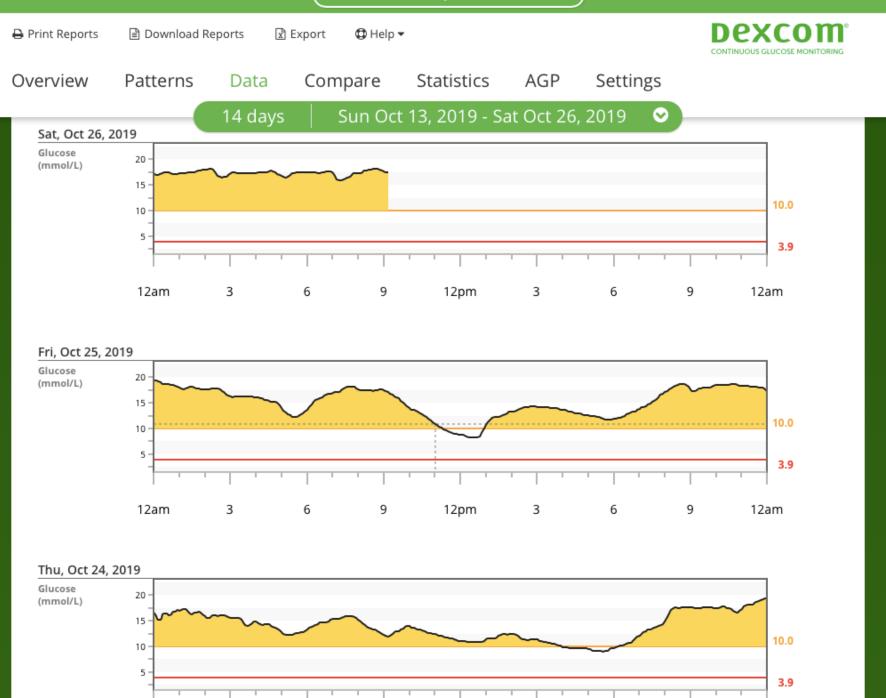
- On Medtronic pump
- Does not like the sensor
- Hyperfear; had lows earlier in her diabetes career;
 prefers 15???

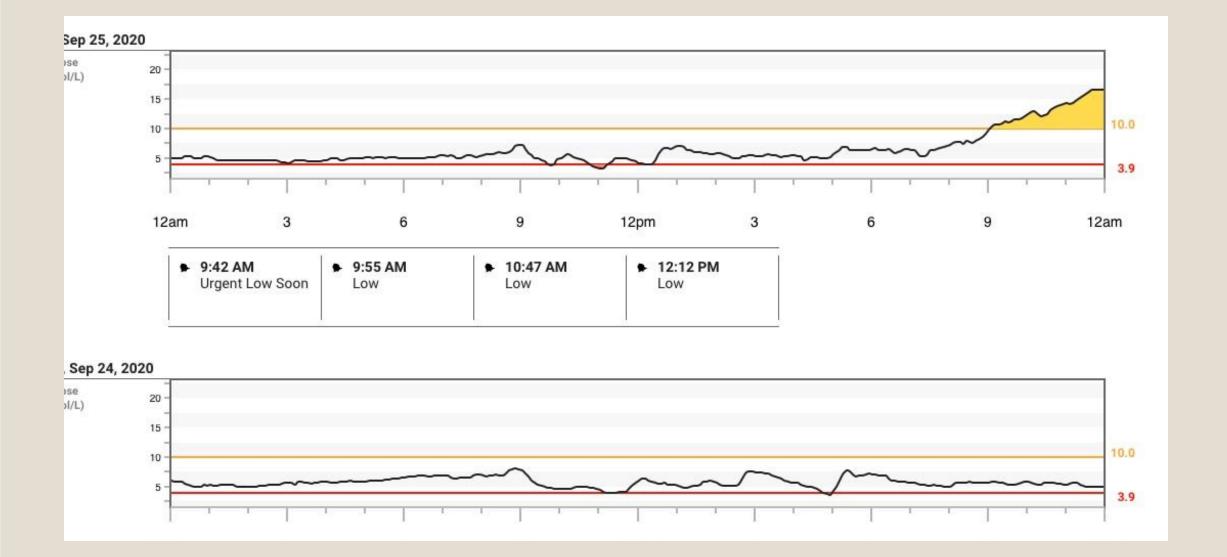
Dexcom[®]
CONTINUOUS GLUCOSE MONITORING

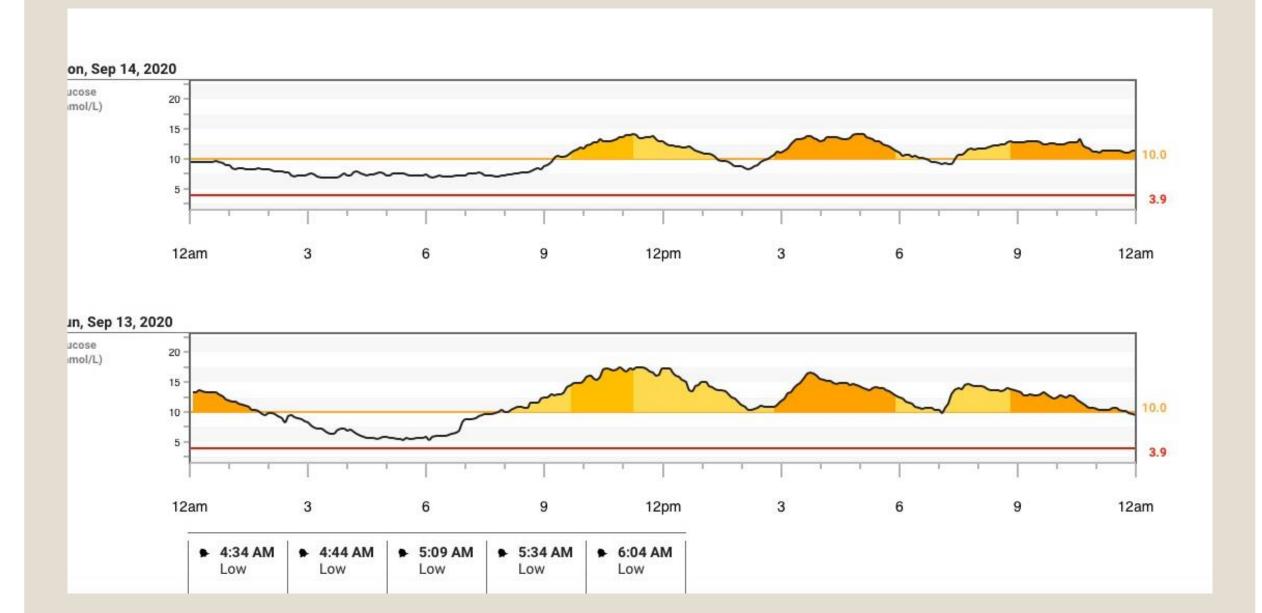


We found no patterns during this date range. The best day was October 24, 2019.















Average Glucose

12.7 mmol/L

Standard Deviation

4.2 mmol/L

Estimated A1C

9.6%

Time in Range



Target Range: 3.9-10.0 mmol/L

Sensor Usage

Days with CGM data

86%

12/14

Avg. calibrations per day

0.0

Automated Insulin Devices

In developmemivestigational/ not approved in canada



In development, Omnipod
 Horizon with algorithm in pod
 designed to receive Dexcom G6
 and future G7 readings and
 automate insulin rates. *1



 In development, Tidepool version of Loop intended to be an FDA regulated mobile App currently being studied with Medtronic and Dexcom CGM.*2,3





In development, Beta Bionics iLet. *4



 In development, Ypsomed mylife YpsoPump*5

https://investors.dexcom.com/news-releases/news-release-details/dexcom-and-insulet-announce-commercial-agreement-integrate https://www.tidepool.org/loop/ https://www.clinicaltrials.gov/ct2/show/NCT03838900 https://www.betabionics.com/technology https://www.mylife-diabetescare.com/en/community/mylife-stories/mylife-stories-detail/cgm-integration-into-mylife-diabetescare-therapy-system.html https://www.ypsomed.com/en-CA/news-details/ypsomed-partners-with-jdrf-to-develop-new-open-technologies-for-next-generation-automated-insulin-delivery-aid-systems.html
Appr. HCP -HCP Only 09.25.20

Automated Insulin Devices

Available globandy approved in canada



In Canada, Basal-IQTM receives
 Dexcom G6 readings to automate basal rates¹, and in US, Control-IQTM* adds automated correction boluses, using Tandem pump. *2



In Canada, Medtronic 670G receives
 Guardian sensor readings (requires
 calibration) to attenuate basal rates ³,
 and in EU, Medtronic 780G* adds
 automated correction boluses. *4



receives Dexcom G6 readings to automate basal rates and deliver manual boluses, using Diabecare RS pump.*5



In **France**, Diabeloop* receives Dexcom G6 readings to attenuate basal rates, using Dana pump. *6

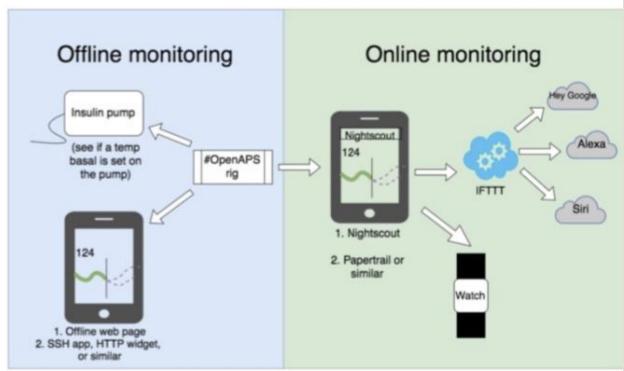
*Alternate controller enabled insulin pump.

1 https://www.tandemdiabetes.com/en-ca/home 2 https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-interoperable-automated-insulin-dosing-controller-designed-allow-more-choices 3 https://www.medtronic.com/ca-en/diabetes/home/products/insulin-pumps/minimed-670g.html 4 https://newsroom.medtronic.com/news-releases/news-release-details/medtronic-secures-ce-mark-minimedtm-780g-advanced-hybrid-closed 5 https://camdiab.com/ 6 https://www.diabelgap.com/6 https:/

Do-It-Yourself Hybrid Closed-Loop Systems

- Available DIY HCL Systems:
 - Open APS
 - Android APS
 - Loop



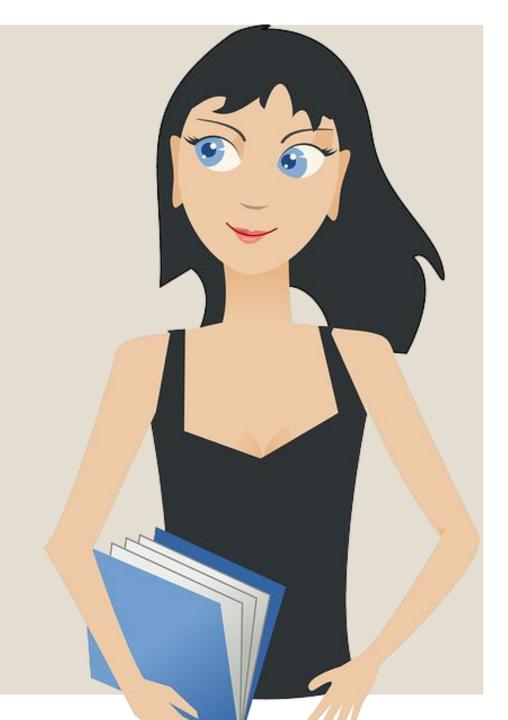


APS, artificial pancreas system; DIY, do-it-yourself; HCL, hybrid closed loop.



AB

- DIAGNOSED AS GDM DURING PREGNANCY
- HER BROTHER IS MY PATIENT
- ANTI GAD VERY HIGH
- CPEPTIDE PRESENT
- POST PARTUM ON TRESIBA 10 UNITS
- 1/10 IC
- ICR 1/4
- HATES BEING HIGH

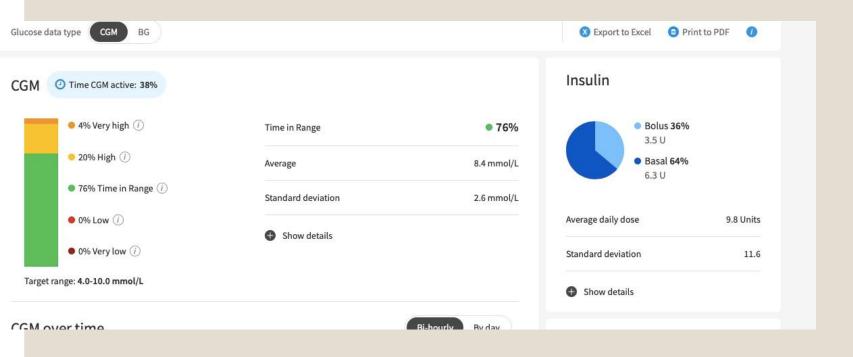


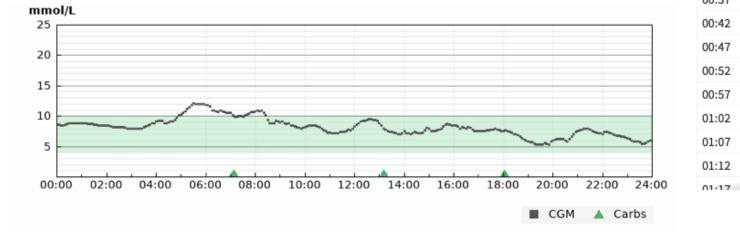
Omnipod DASH

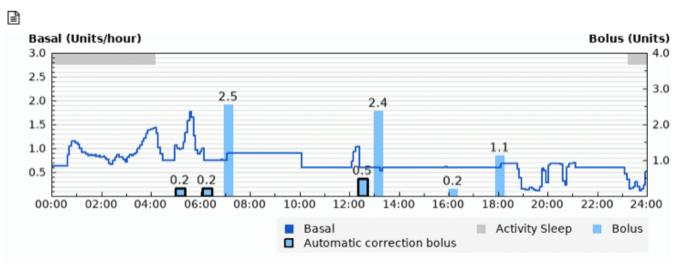


- Integrated glucose testing: Ascensia Contour wireless connection with DASH
- Bolus dose calculator uses carbohydrates, blood glucose, and insulin on board
- Optional bolus presets for small, medium, large meals
- Bolus delivery rate: 40 seconds per unit
- Extended bolus can be delivered between 0.5-6 hr
- Omnipod DASH has Calorie King integration

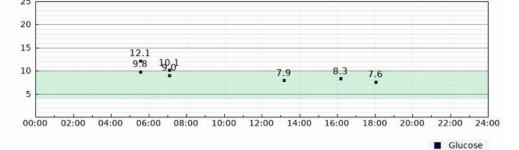


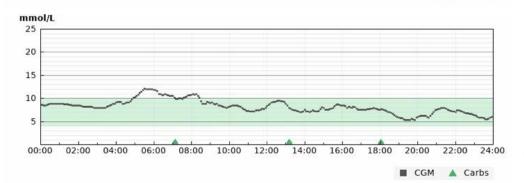


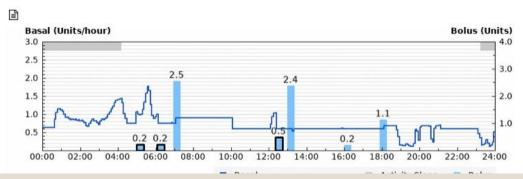










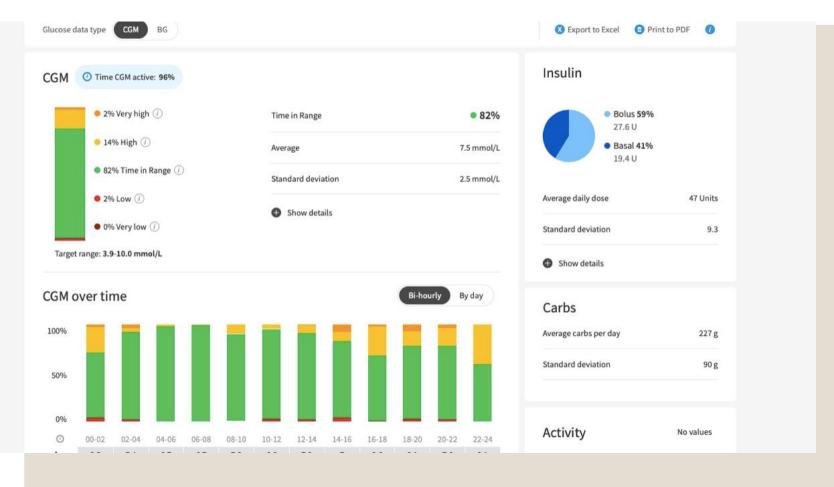


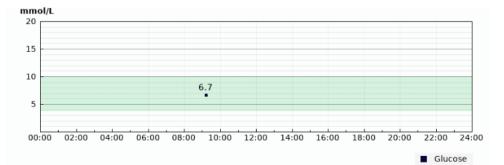


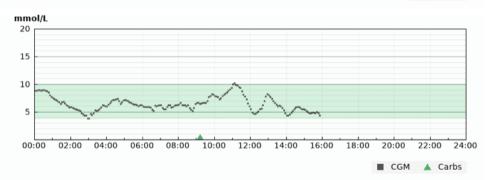
Basal		Bolus	Expand 🕶
Time	U/h	Time	U
00:02	0.625	04:58	0.23
00:37	0.862	(Corr:	0.23)
00:42	1.044	(IOB:	0.42)
00:47	1.153	06:03	0.23
00:52	1.148	(Corr:	0.23)
00:57	1.113	(IOB:	0.77)
01:02	1.079	07:07	2.55
01:07	0.992	(Meal:	2.55)
01:12	0.915	(IOB:	0.52)
01-17	0.024	12:20	0.48

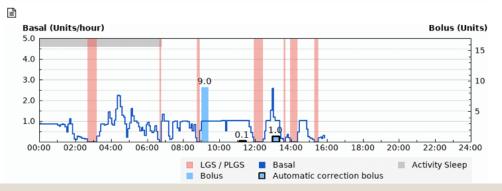
Carbohydrates

Time	
07:07	51g
13:10	50g
18:03	28g











Basal		Bolus	Expand 🕶
Time	U/h	Time	U
00:01	0.875	09:12	8.96
00:06	0.850	(Corr:	0.21)
01:01	0.811	(Meal:	8.75)
01:06	0.762	11:06	0.14
01:11	0.832	(Corr:	0.14)
01:16	0.848	(IOB:	3.49)
01:21	0.845	12:57	0.97
01:26	0.716	(Corr:	0.97)
01:31	0.471		
01-26	0.050		

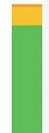
Carbohydrates

Time		
09:12	70g	





CGM (



Target rai

CGM ove

100%

50%

Basal (Units/hour)

5.0

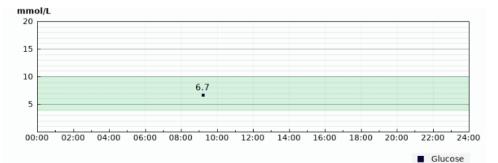
4.0

3.0

2.0

0%

0





 $00:00 \quad 02:00 \quad 04:00 \quad 06:00 \quad 08:00 \quad 10:00 \quad 12:00 \quad 14:00 \quad 16:00 \quad 18:00 \quad 20:00 \quad 22:00 \quad 24:00$ LGS / PLGS Basal

Automatic correction bolus

Bolus



Bolus (Units)

Activity Sleep

15

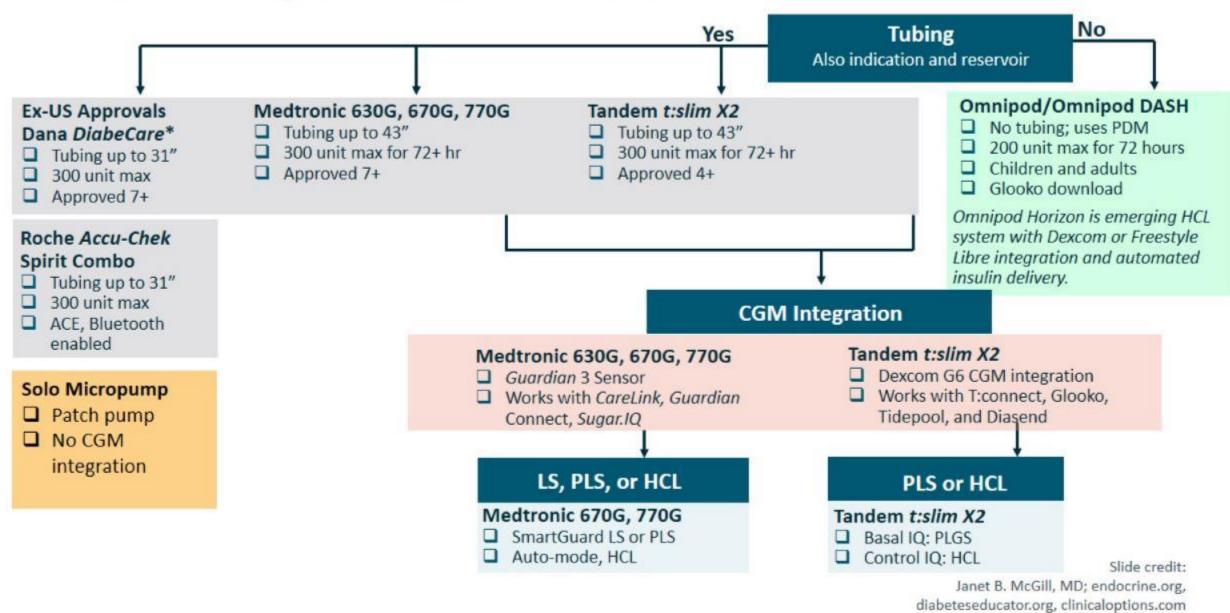
10

Basal		Bolus	Expand 🕶
Time	U/h	Time	U
00:01	0.875	09:12	8.96
00:06	0.850	(Corr:	0.21)
01:01	0.811	(Meal:	8.75)
01:06	0.762	11:06	0.14
01:11	0.832	(Corr:	0.14)
01:16	0.848	(IOB:	3.49)
01:21	0.845	12:57	0.97
01:26	0.716	(Corr:	0.97)
01:31	0.471		
01.26	0.050		

Carbohydrates	
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Time	
09:12	70g

Which Pump for Which Patient?



Available in Canada Glucose Sensor Systems

Intermittent
Abbott FreeStyle Libre



Continuous Dexcom G5/G6



Continuous Medtronic Enlite 2/ Guardian 3



Smart pen*summetapproved in canada

Track when and how much insulin was injected





 In US, Companion Medical bluetooth enabled smart pen connects with US Dexcom Clarity. *1,2



In development, Novo Nordisk smart pens. *3





In development, Lilly smart pen designed to integrate with Dexcom. *3,4

Accessed September 23 2020:

https://diatribe.org/keep-track-your-insulin-doses-bluetooth-enabled-smart-insulin-pen-now-available-pharmacies

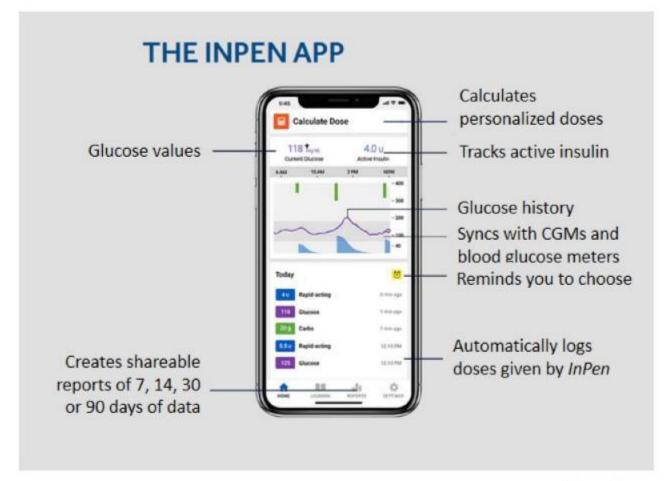
https://diatribe.org/latest-news-diabetes-10-highlights-easd-2019

https://investors.dexcom.com/static-files/65d78bca-f16d-4fb6-99c5-c3753f4a2801

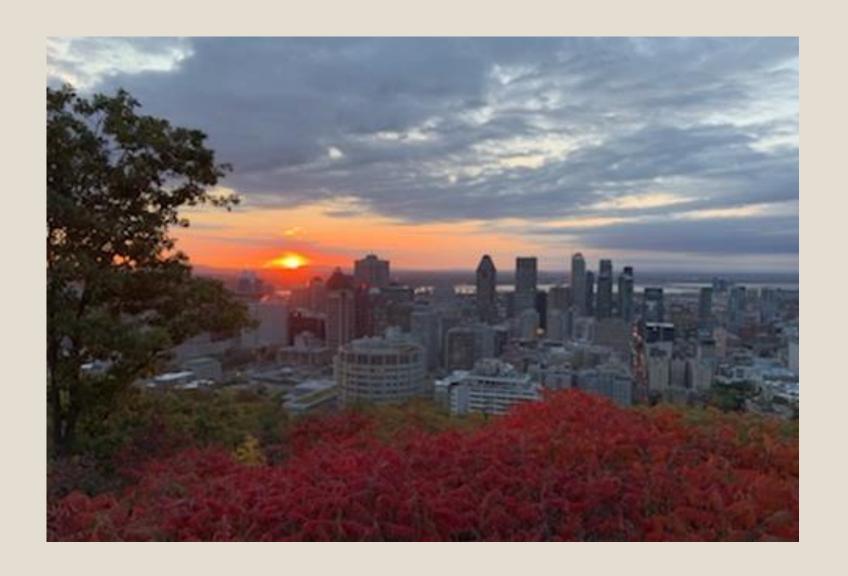
https://provider.dexcom.com/industry-news/dexcom-announces-development-agreement-lilly-integrate-dexcom-cam-connected-diabetes

Medtronic *InPen*: Insulin Dose Calculator + Integrated System + App

Combines reusable Bluetoothenabled insulin pen with mobile app Compatible with Nobolog, Humalog, and Figsp cartridges (not included) Connects to the app via Bluetooth Monitors insulin temperature Battery lasts a full year with no need to charge Delivers half-unit doses



Slide credit: Janet B. McGill, MD; endocrine.org, diabeteseducator.org, clinicaloptions.com



TECHNOLO GY CASES UPDATE