



Brigham and Women's Hospital

Founding Member, Mass General Brigham

Advances in Diabetes Technology

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Boston University School of Medicine, Boston, Massachusetts

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Associate Director of Acute Diabetes Care

- Clinical focus: Diabetes, Endocrine Disease in Pregnancy
- Research focus: barriers to diabetes care, transition of care, system improvement and development of innovative models of diabetes care



DISCLOSURES

Co-Investigator, Effectiveness and Safety of Dexcom G6 Continuous Glucose Monitoring System in Non-Critically Ill Patients in the Inpatient Setting [PTL-904283]



OBJECTIVES

- Review available options for diabetes technology (CGM, insulin pump, smart pen, other insulin delivery devices)
- Discuss patient populations that may benefit from this adjunct to their diabetes treatment and how use may be incorporated into clinical practice



Case 1

72-year-old female with longstanding type 2 diabetes

No known diabetes-related microvascular complications

Diabetes regimen: metformin 1000 mg BID, glargine 15 units qHS, glipizide 5 mg BID

Does not check FSBG *“doesn’t like to poke finger...hurts too much”*; HbA1c 8.6%

Routine visit: family member shares patient complaints of headaches

“light-headed” “dizzy”- early morning, late afternoon, bedtime

symptoms often improve after eating

During visit suggested FSBG monitoring, especially when having symptoms

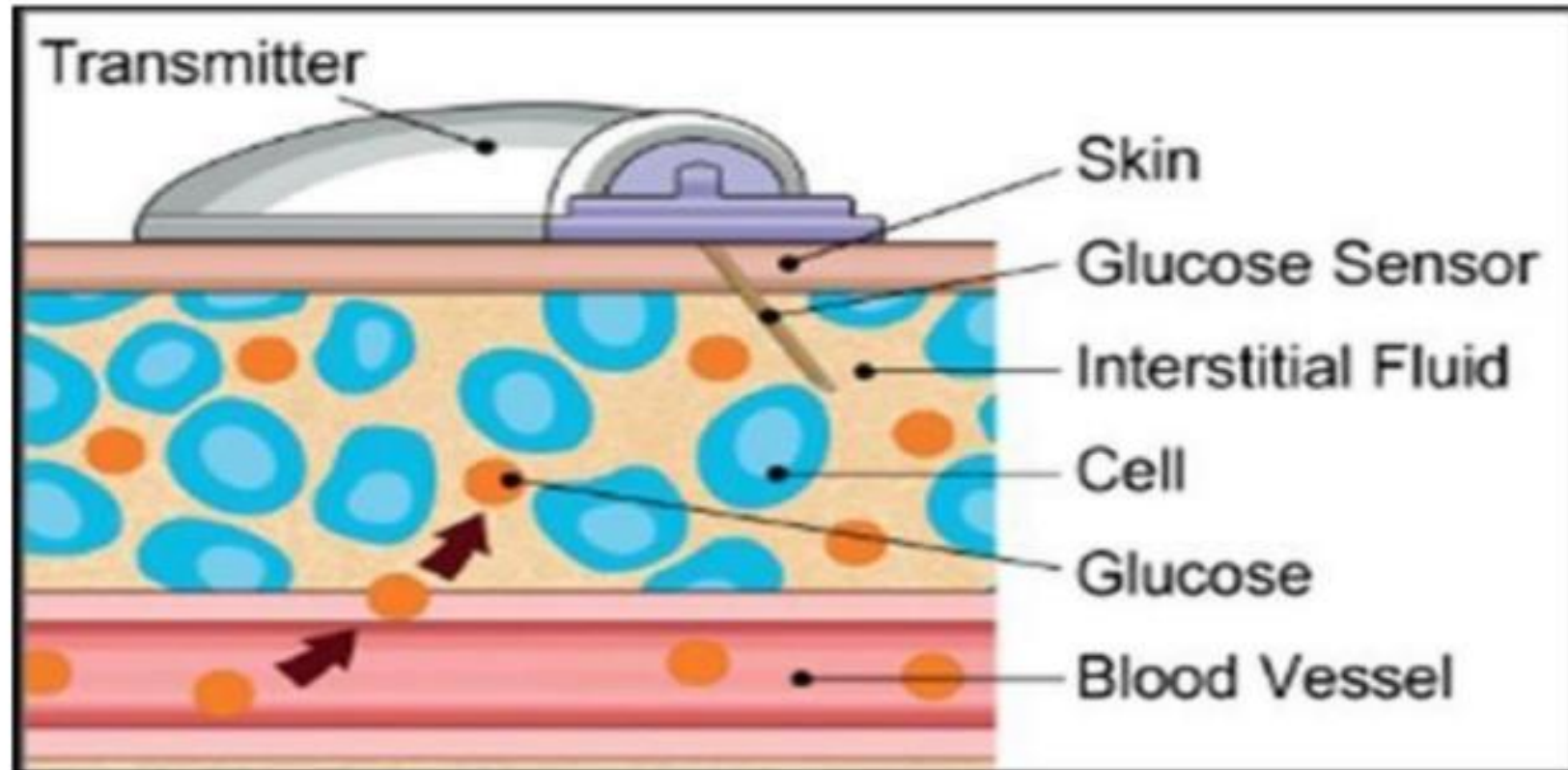
Follow-up call SMBG: 76, 52, 49*, 67, 42* mg/dL

*requiring assistance by family



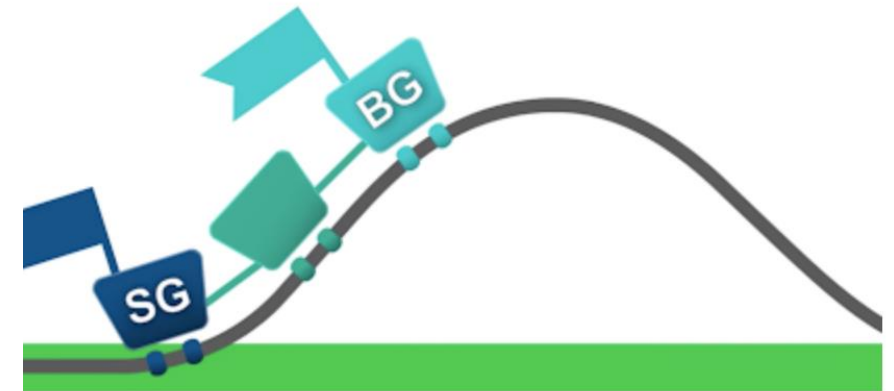
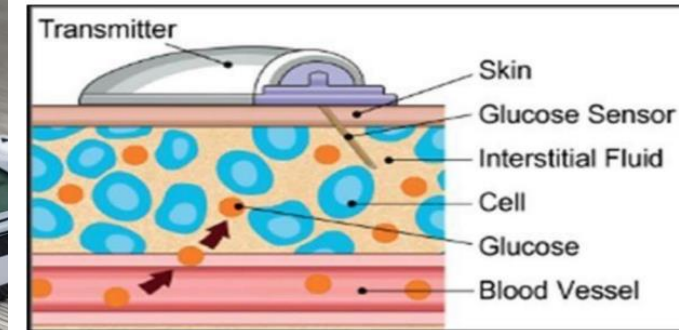
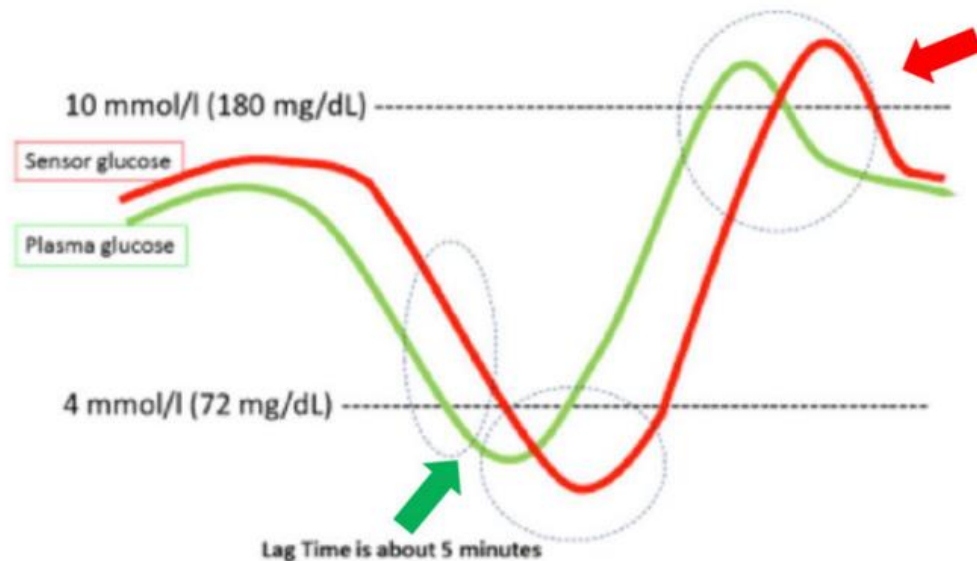
Is patient a candidate for Continuous Glucose Monitor (CGM)?

What is continuous glucose monitoring (CGM)?



CGM: Is this the same as fingerstick glucose monitoring?

Differences – plasma vs sensor



Fingerstick Glucose Monitoring vs. CGM

Finger stick (capillary BG): glucose at “point in time”

CGM (interstitial BG): current BG, glucose trend on device receiver or smartphone
directional guidance (arrows to reflect rate of change)
alerts when BG out of target (individualized), alarm for hypoglycemia

- Interaction with insulin pumps (CSII with SAP, CSII with AID)
- Storage of historic data and ability to share with health care team, caregivers
- Patient satisfaction (CGM insertion q 10-14d vs FS pending monitoring program)



CSII: continuous subcutaneous insulin infusion

SAP: sensor augmented pump

AID: automated insulin delivery

Case 1 *Is patient a candidate for CGM?*

72-year-old female with longstanding type 2 diabetes
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- A. Yes, insurance will cover CGM
- B. Yes, but insurance will not cover CGM
- C. No, patient is not on multiple injections of insulin per day/insulin pump therapy
insurance will not cover CGM



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Expanded Criteria for CGM in April 2023

Medicare eligibility criteria

Individuals **diagnosed with diabetes** and meets one of the following criteria:

- Is treated with any **insulin**, or
- Has a history of problematic **hypoglycemia**, with documentation of at least one of the following:

One or more Level 2 hypoglycemic events (glucose <54mg/dL) that persist despite one or more modifications of the diabetes treatment plan and/or adjustment of medication

OR

One Level 3 hypoglycemic event (glucose <54mg/dL) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

Patient has an in-person or Medicare-approved visit with the practitioner prescribing the CGM *within 6 months of initiating CGM therapy*

Patient has an in-person or Medicare-approved visit with the practitioner who prescribed the CGM *every 6 months after initiating CGM therapy*.



Expanded Criteria for CGM: non-insulin treated patients

For criterion 4B, the treating practitioner's medical record must document the beneficiary has a history of problematic hypoglycemia consistent with one of the following pathways to coverage:

1. Beneficiaries with non-insulin treated diabetes and a history of recurrent (more than one) level 2 hypoglycemic events

- a. The treating practitioner must document at least one of the following in the medical record for each event:
 - i. The glucose values for the qualifying event(s) (glucose <54mg/dL (3.0mmol/L)); or,
 - ii. Classification of the hypoglycemic episode(s) as level 2 event(s); or,
 - iii. Incorporate a copy of the beneficiary's BGM testing log into the medical record reflecting the specific qualifying events (glucose <54mg/dL (3.0mmol/L)); and,
- b. Documentation of more than one previous medication adjustment and/or modification to the treatment plan (such as raising A1c targets) prior to the most recent level two event.

2. Beneficiaries with non-insulin treated diabetes and a history of at least one level 3 hypoglycemic event

- a. The treating practitioner must document at least one of the following in the medical record:
 - i. The glucose value for the qualifying event (glucose <54mg/dL (3.0mmol/L)); or,
 - ii. Classification of the hypoglycemic episode as level 3 event; or,
 - iii. Incorporate a copy of the beneficiary's BGM testing log into the medical record reflecting the specific qualifying event (glucose <54mg/dL (3.0mmol/L)); and,
- b. An indication in the medical record that the beneficiary required third party assistance for treatment.



Are the different types of CGM?

Professional/Diagnostic CGM

In office set up for 7-14 day study, “blinded”

CGM to assist with glucose pattern detection/medication adjustments; trial for personal use

Personal CGM

Intermittent “flash” continuous glucose monitoring (isCGM):

patient needs to “swipe” receiver/smartphone over device to obtain data

Real time continuous glucose monitoring (rtCGM):

automatically transmits CGM data to receiver/smartphone

Considerations for patients when selecting CGM:

Ability to provide alerts when out of range and/or for hypoglycemia prevention

Ability to interact with insulin pumps

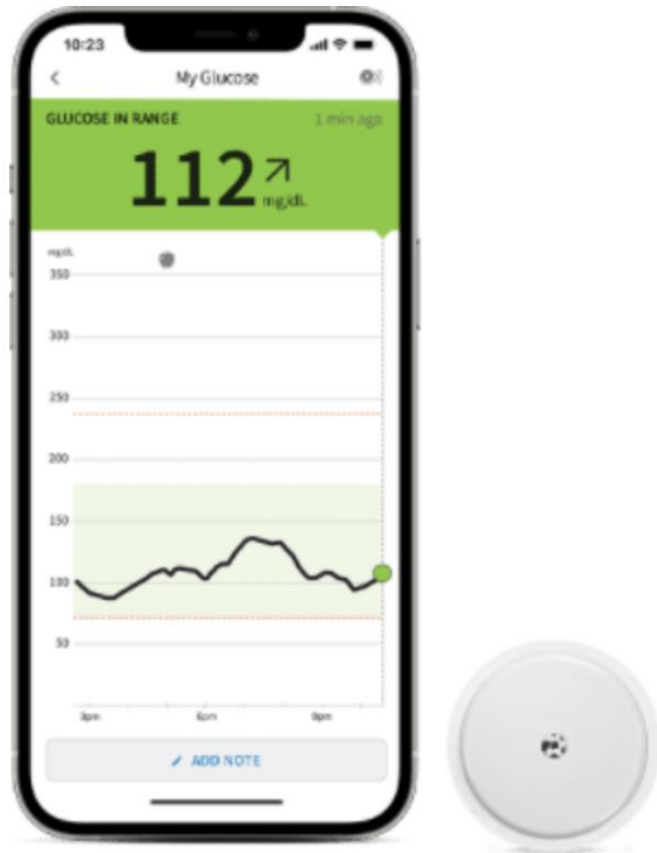


Continuous Glucose Monitoring: Dexcom



Continuous Glucose Monitoring: Freestyle Libre

Libre 2



Libre 3/Libre 3 Plus



Continuous Glucose Monitoring: Medtronic Guardian



Guardian



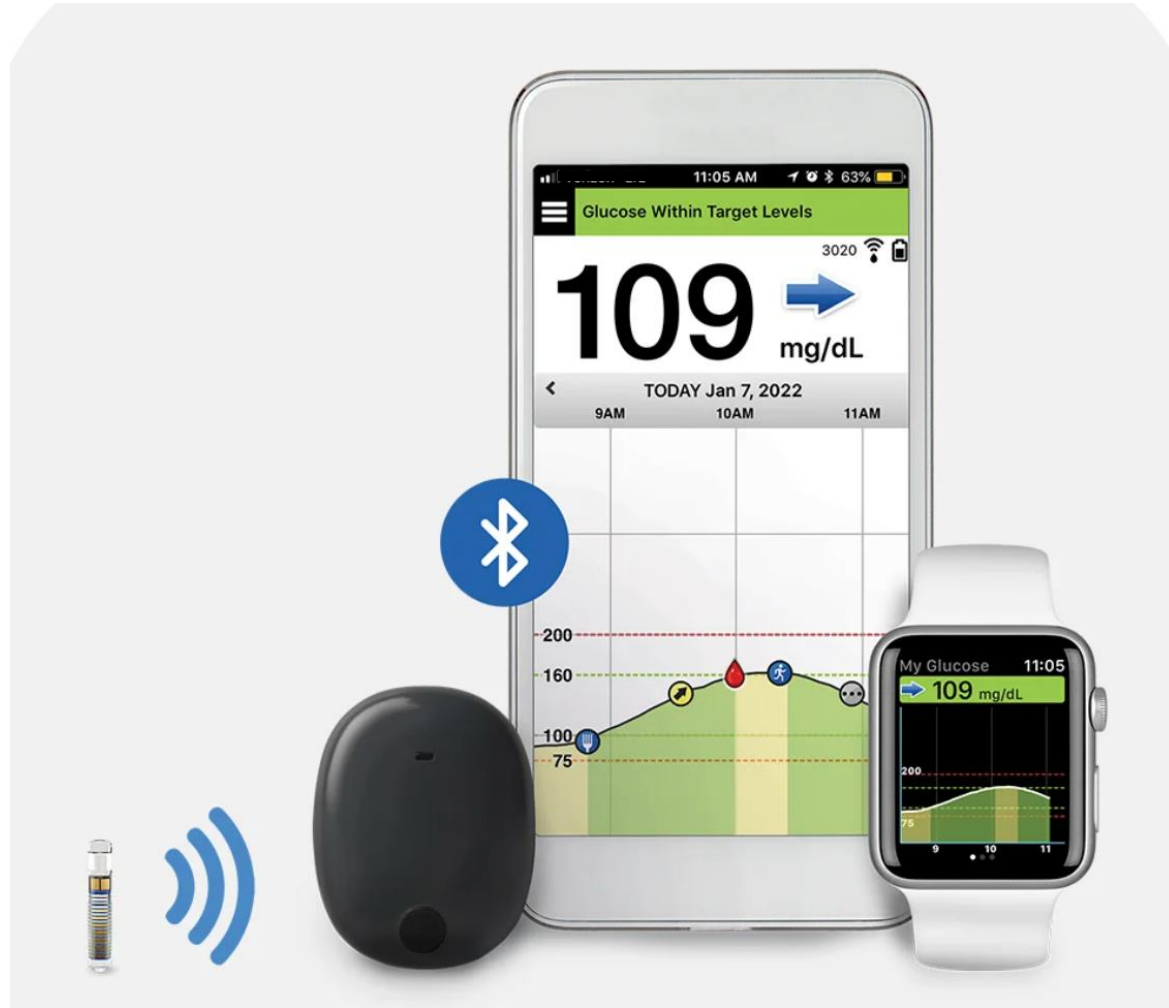
CGM Directional Guidance and Real Time Data for Medication Adjustments

Medtronic	Dexcom	Libre	Change in glucose (mmol/l) in 15 mins	Description	Insulin dose adjustment during mealtime
	→	→	0 - 0.8	Stable	Give usual mealtime insulin
↓	↘	↘	0.8 – 1.7	Falling slowly	Give 10 % less than usual mealtime insulin
↓↓	↓	↓	1.7 – 2.5	Falling quickly	Give 20 % less than usual mealtime insulin
↓↓↓	↓↓		> 2.5	Falling rapidly	Give 20-30 % less than usual mealtime insulin
↑	↗	↗	0.8 – 1.7	Rising slowly	Give 10 % more than usual mealtime insulin
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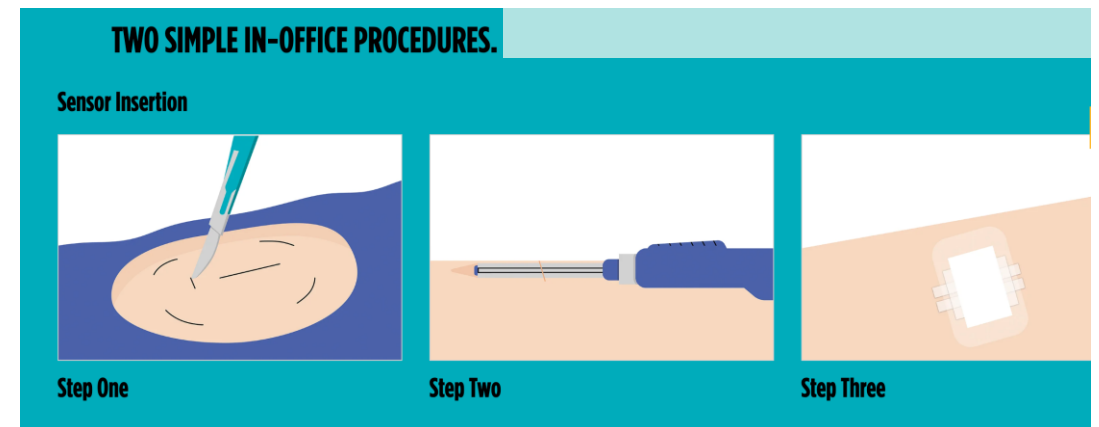
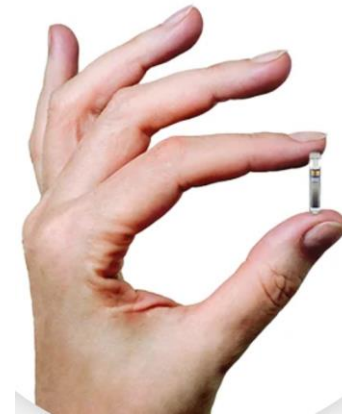
Insulin dose adjustments for trend arrows for various CGM devices



Continuous Glucose Monitoring: Eversense



Implantable
E3 Change q6 months
E365 change every year



Continuous Glucose Monitoring: Data Review and Metrics

R1.1.1 Established clinical targets should be used to individualize glycemic targets and adjust therapy based on each individual's overall health status, medical condition (eg, pregnancy, frailty), and risk for hypoglycemia:

All Persons with Diabetes

- Number of days of active CGM use: 14 days preferred
- Percentage of data available from active CGM use: >70% of data from 14 days
- Mean glucose: Individualized to targets
- Glucose management indicator (GMI): Individualized to targets
- Glycemic variability, percent coefficient of variation (%CV [coefficient of variation]): $\leq 36\%$

Type 1 Diabetes (T1D)/Type 2 Diabetes (T2D)

- Percentage of time in range (%TIR) 70 to 180 mg/dL: >70%
- Percentage of time below range (%TBR) <70 mg/dL: <4%
- %TBR <54 mg/dL: <1%
- Percentage of time above range (%TAR) >180 mg/dL: <25%
- %TAR >250 mg/dL: <5%

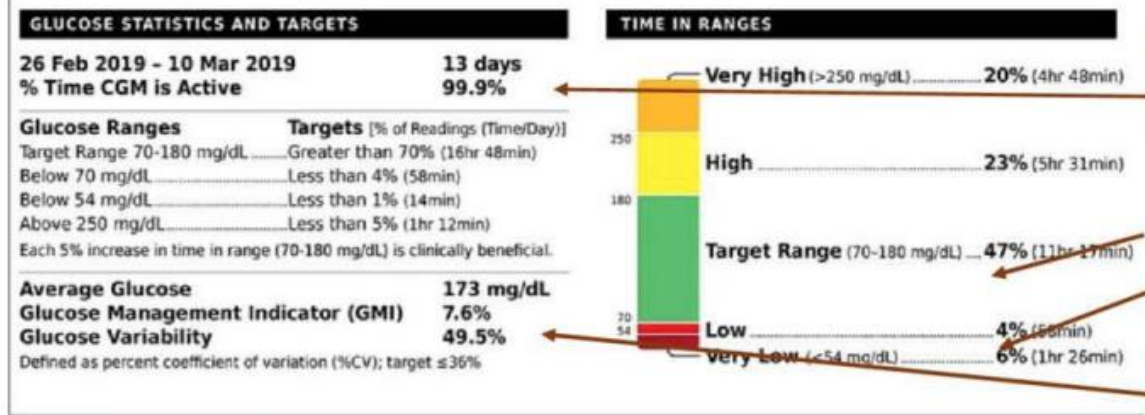
Older/High Risk T1D/T2D

- %TIR 70 to 180 mg/dL: >50%
- %TBR <70 mg/dL: <1%
- %TBR <54 mg/dL: ~0%
- %TAR >250 mg/dL: <10%

Pregnancy: T1D

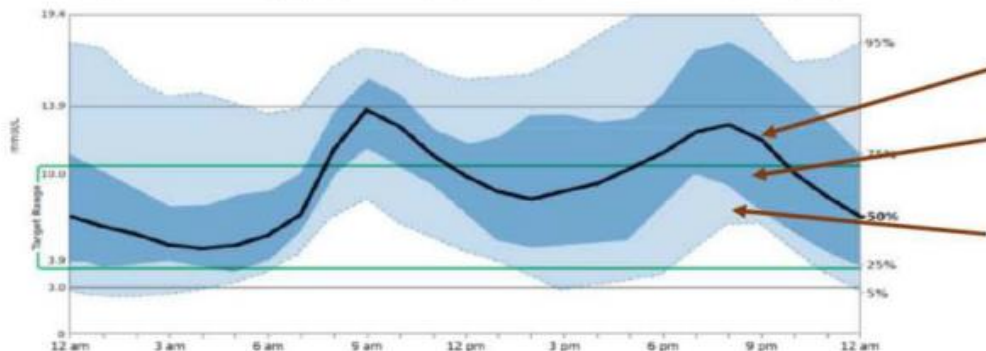
- %TIR 63 to 140 mg/dL: >70%
- %TBR <63 mg/dL: <4%
- %TBR <54 mg/dL: <1%
- %TAR >140 mg/dL: <25%



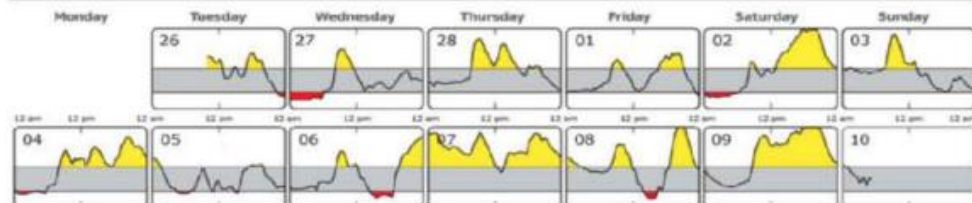


AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.



DAILY GLUCOSE PROFILES



Each daily profile represents a midnight-to-midnight period.

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Ambulatory Glucose profile (AGP) report is displayed for 14 days of sensor wear. It correlates well to 3 months of *CGM data
CGM is active 99.9% of time. Recommendation is for min 70% usage (10 days) for reliable data

Time in range (TIR)- aim is to slowly increase time spent in range. TIR (3.9-10mmol/l) of 70% correlates to HbA1c of 53 mmol/mol
Aim for low (<3.9 mmol/l) to be limited to < 5% and very low (<3.0mmol/l) to be <1%

Glucose Management Indicator (GMI)- Provides with estimated HbA1c
Glucose variability (GV)- refers to how much the glucose readings varies from mean or median glucose. Low GV indicates stable glucose profile

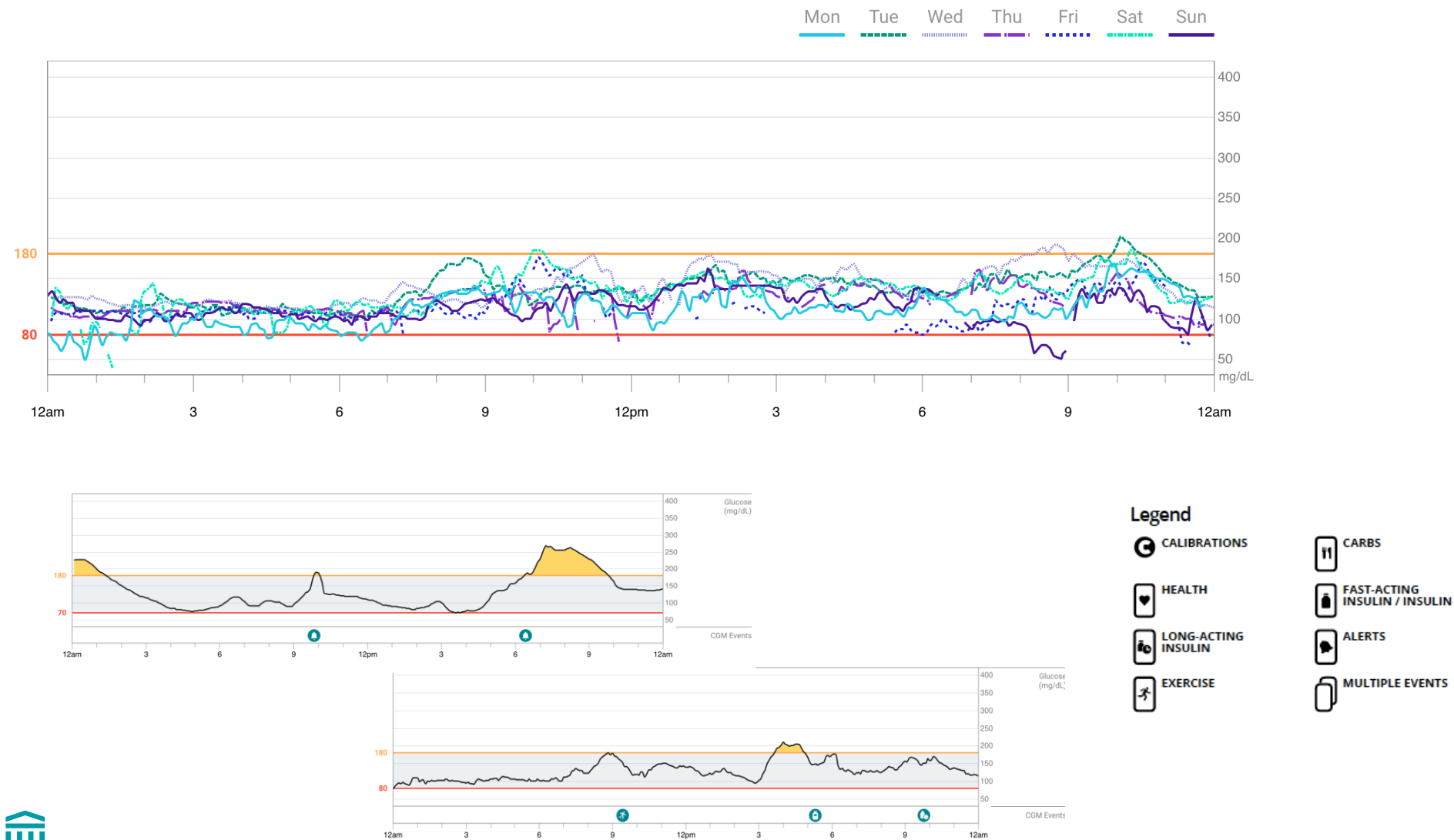
Ambulatory glucose profile: The **solid line** is the median or 50% line; half of all glucose values are above and half are below this value.
The 25th and 75th percentile curves shaded in **dark blue** represent the interquartile range or 50% of all values and are a good visual indicator of the degree of GV.
The dashed outer lines (the 10th to 90th percentile curves) in **light blue** indicate that only 10% of glucose readings were above or below these value

Graph showing daily data. Each daily profile represents midnight to midnight data

Figure 4 Example of an AGP (ambulatory glucose profile).



Cloud based data remote glucose monitoring



Case 1

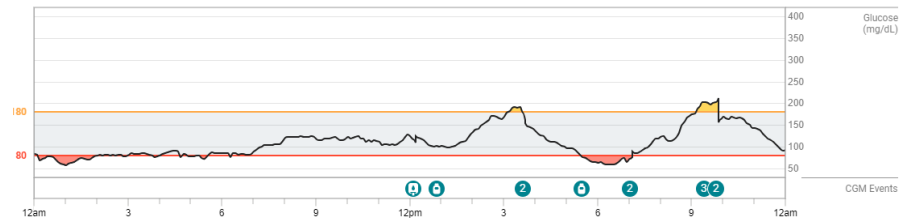
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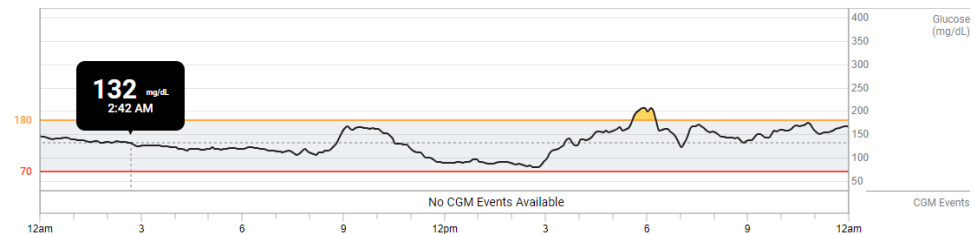
Routine visit: family member shares patient complaints of headaches “light-headed” “dizzy”- early morning, late afternoon, bedtime; symptoms improved after eating

Follow-up call SMBG: 76, 52, 49*, 67, 42* mg/dL
*requiring assistance by family

Started on CGM “loves it”
glipizide and glargine adjusted
no further episodes of hypoglycemia
HbA1c 7.1 % in the subsequent 3 months



Baseline CGM



2w follow-up



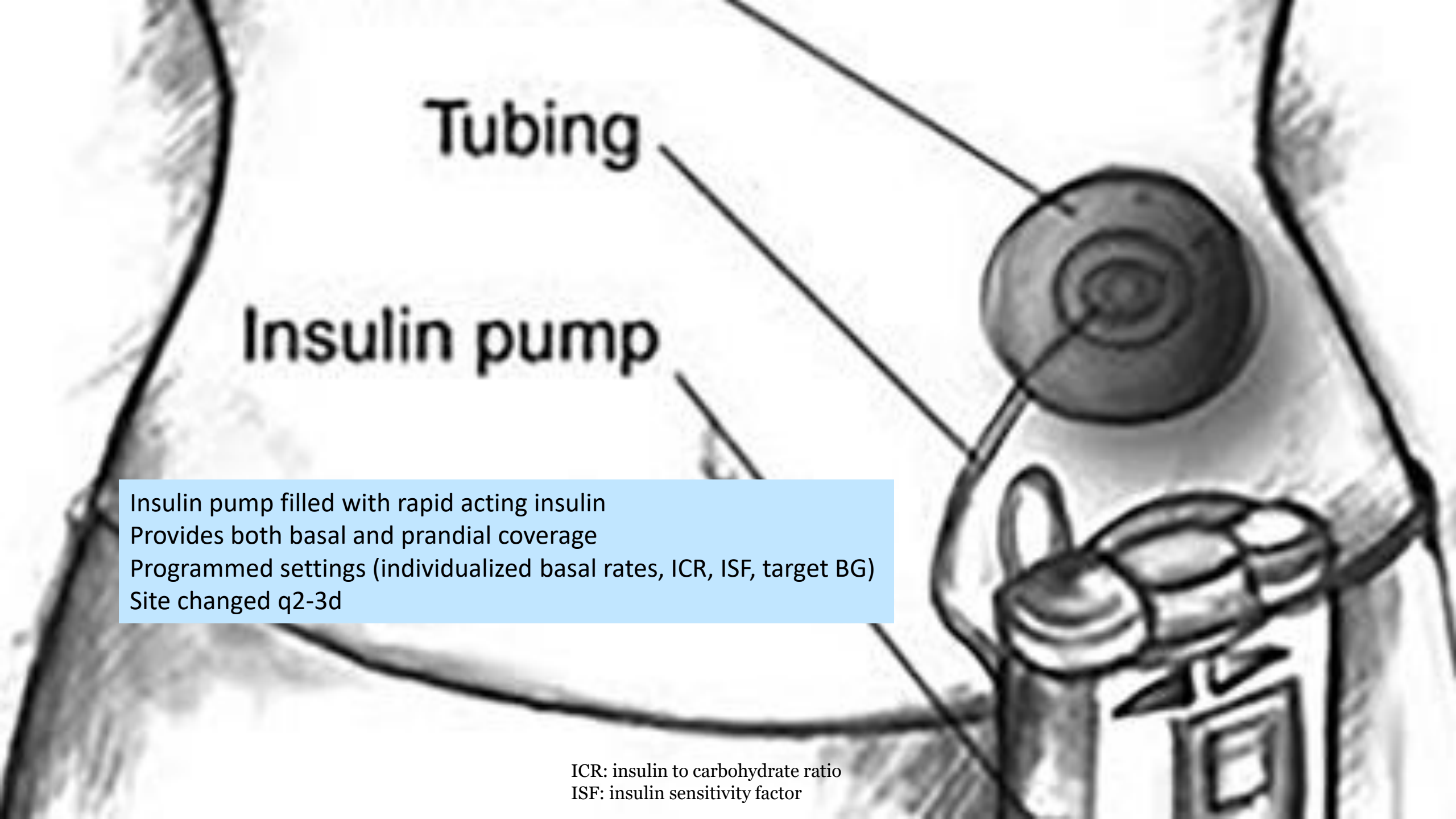
Case 2

57-year-old female with insulin deficient DM type 2
Diabetes complicated by mild NPDR and MAU; HbA1c 9.9%

Diabetes regimen: glargine 24 units qHS and lispro 8-10 units with meals
“Always takes insulin at bedtime, but often misses with meals as doesn’t like to inject in public”

Am I a candidate for an insulin pump?





Tubing

Insulin pump

Insulin pump filled with rapid acting insulin
Provides both basal and prandial coverage
Programmed settings (individualized basal rates, ICR, ISF, target BG)
Site changed q2-3d

ICR: insulin to carbohydrate ratio
ISF: insulin sensitivity factor

Case 2 *Am I a candidate for an insulin pump?*

57-year-old female with insulin deficient DM type 2

Diabetes complicated by mild NPDR and MAU; HbA1c 9.9%

Diabetes regimen: glargine 24 units qHS and lispro 8-10 units with meals

“Always takes insulin at bedtime, but often misses with meals as doesn’t like to inject in public”

A. Yes

B. No



Which patients are candidates for insulin pump therapy?

- Elevated HbA1c
 - Glycemic variability
 - Recurrent hypoglycemia (nocturnal, activity-induced)
 - Hypoglycemic unawareness
 - Dawn phenomenon
 - Gastroparesis
-
- Motivated
 - Diabetes health literacy
 - Technical proficiency
 - Do they count carbs/can they count carbs?



Patient Perspective

“I wish I did this sooner..”

“I could do the things I love like dancing and not have to worry about my sugar...”

“I could go to bed without worrying if I would get low...”

“not scared to give bolus anymore...”

“I could breathe when he plays sports now..”
(parent of type 1)

“Easier than I thought...gave me my life back...”

“Amazing to feel like I have some control back...”

“With a pump I felt like I could keep living my life..”

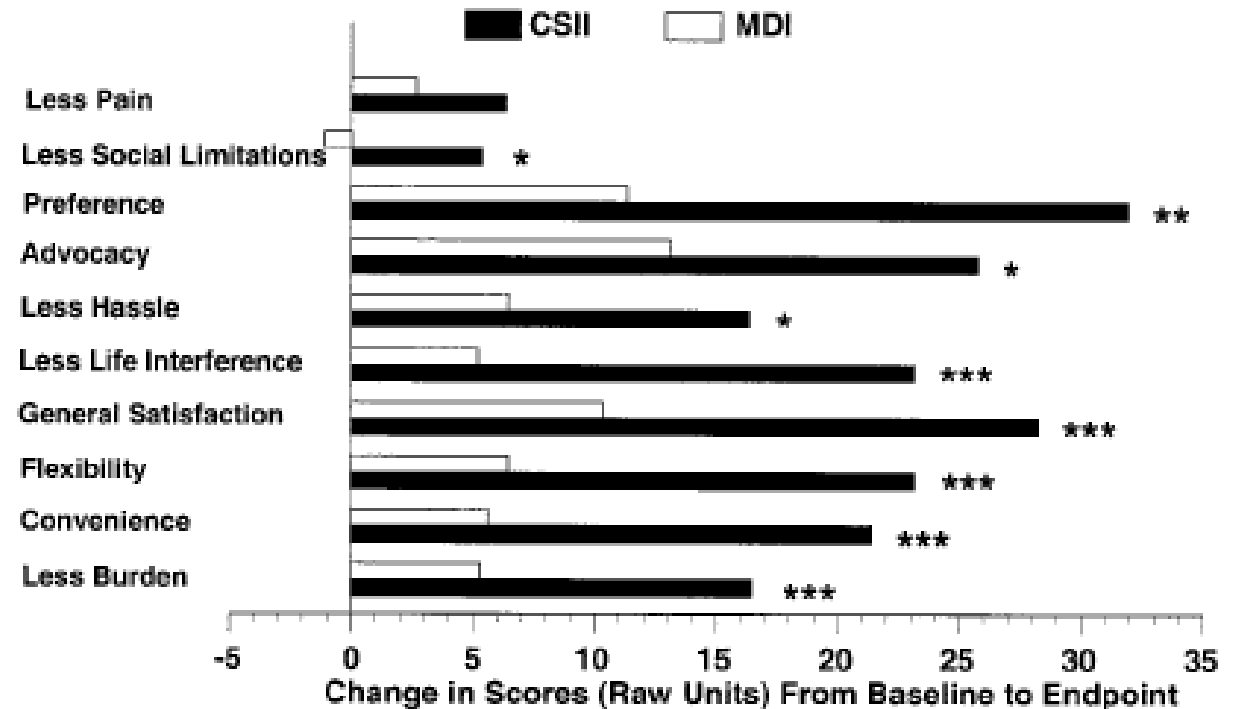
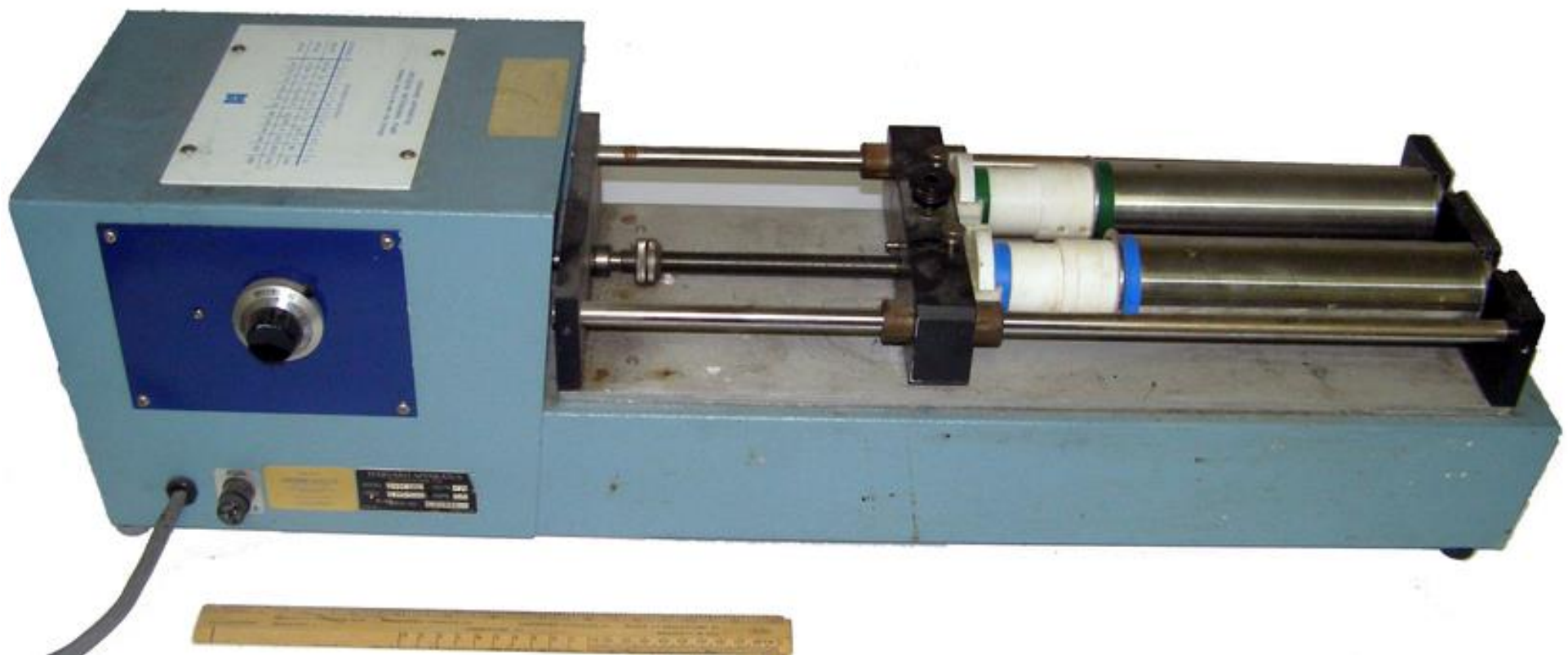
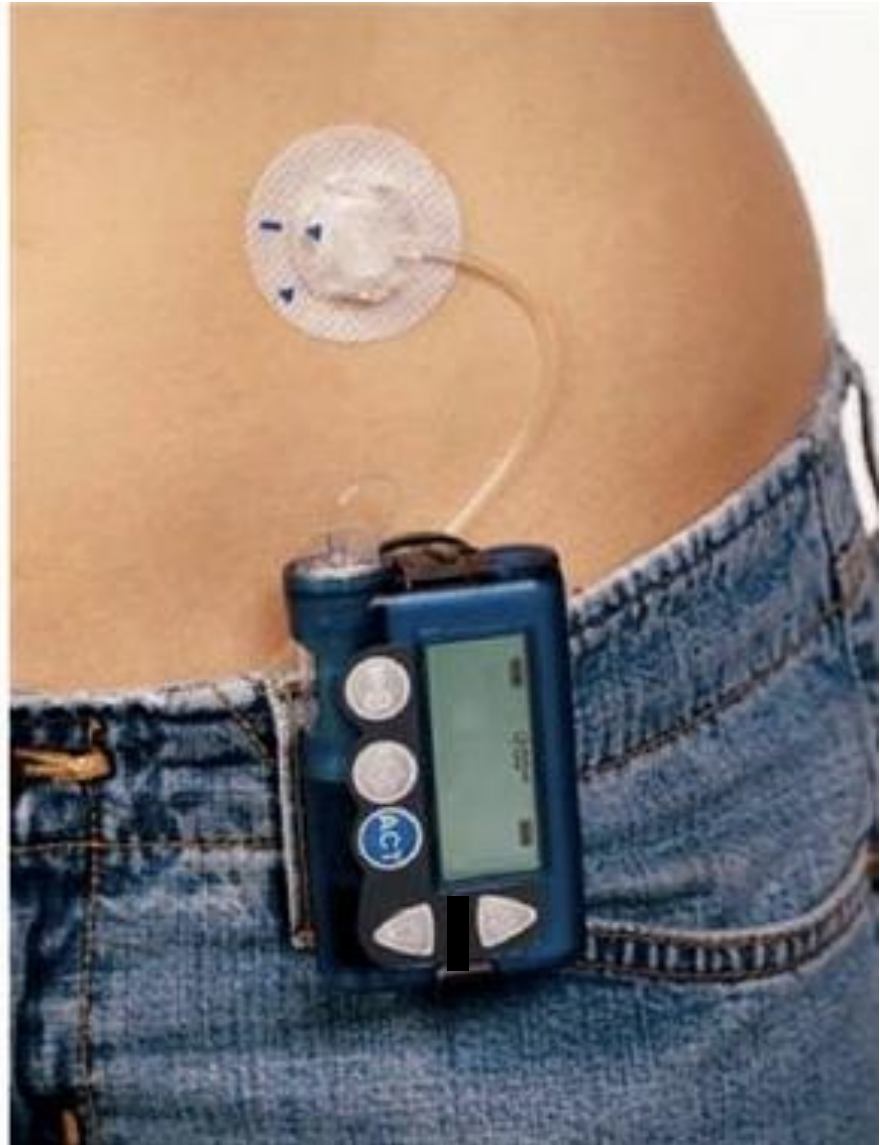


Figure 2— Change-from-baseline improvements in patient satisfaction subscores at the end of the study. Improvements were compared between treatment groups, controlling for patient age. Responses to baseline questionnaires are based on prestudy insulin treatment. Change-from-baseline scores are available for 52 subjects (79%) in the CSII group and 52 subjects (85%) in the MDI group. Scoring of satisfaction categories ranged from 0 to 100 for least to most satisfaction, respectively. *P < 0.025; **P < 0.01; ***P < 0.001.







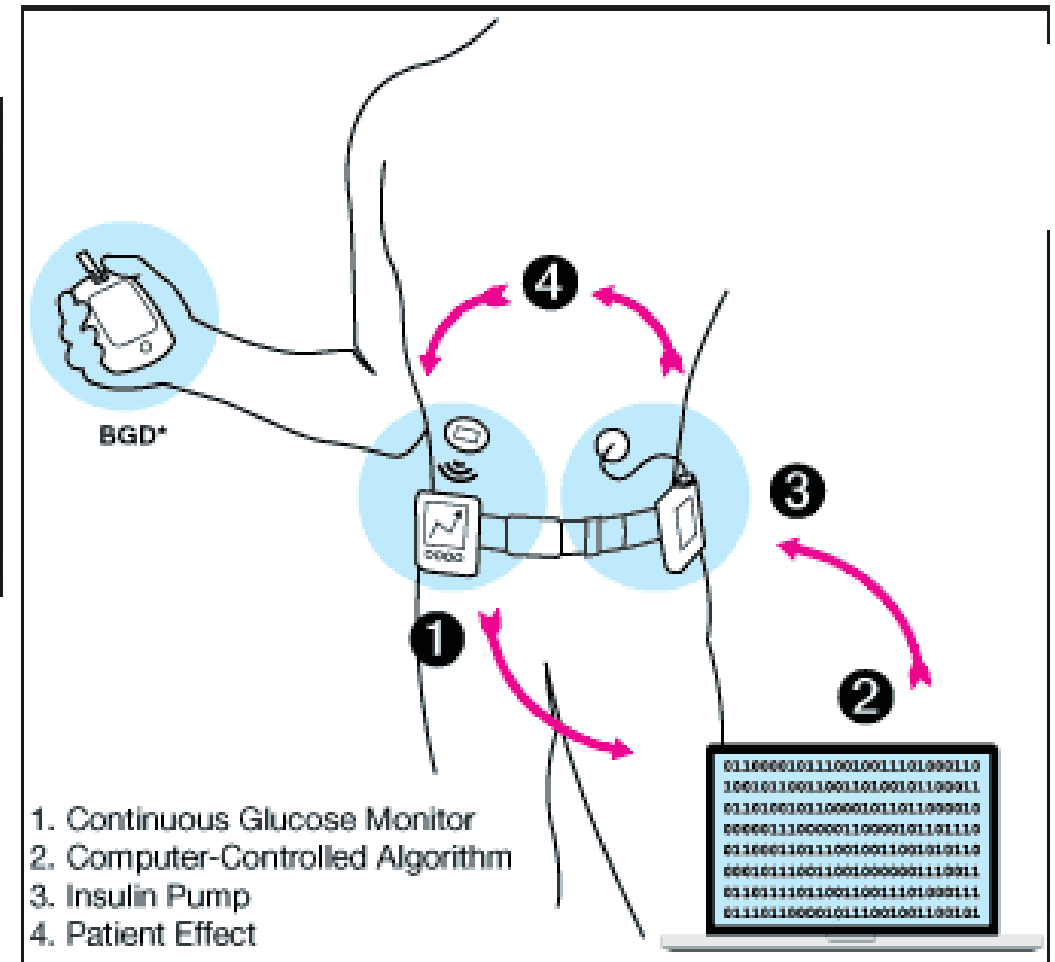
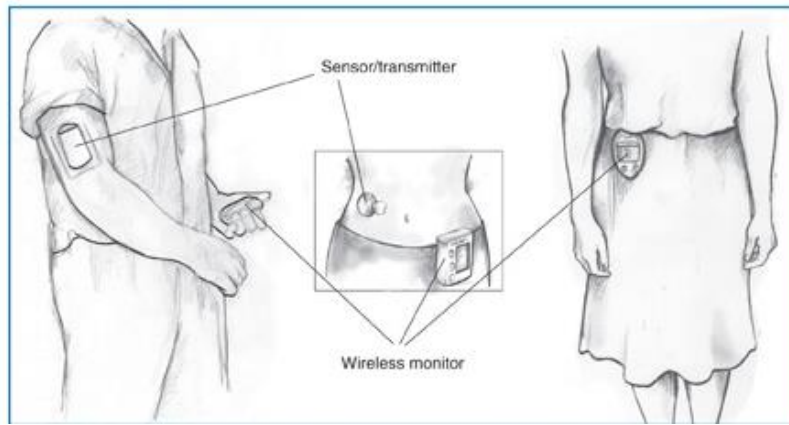
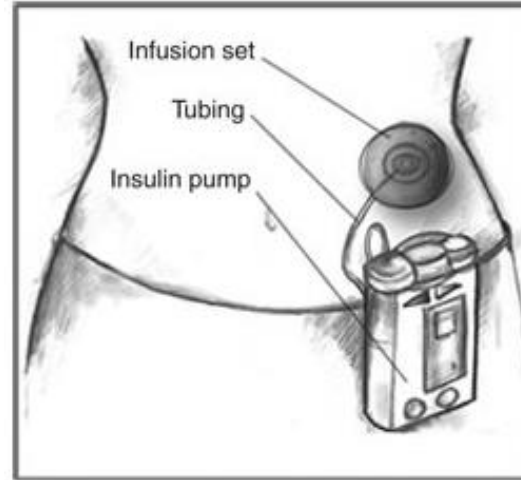
Many options!



<https://www.medtronicdiabetes.com/home>
<https://www.omnipod.com/>
<https://www.tandemdiabetes.com/>

Insulin Pump and CGM

- CSII (insulin pump)
 - CSII with SAP
 - CSII with AID
- (options for manual vs auto mode)



CSII: continuous subcutaneous insulin infusion
 SAP: sensor augmented pump
 AID: automated insulin delivery



CSII with AID



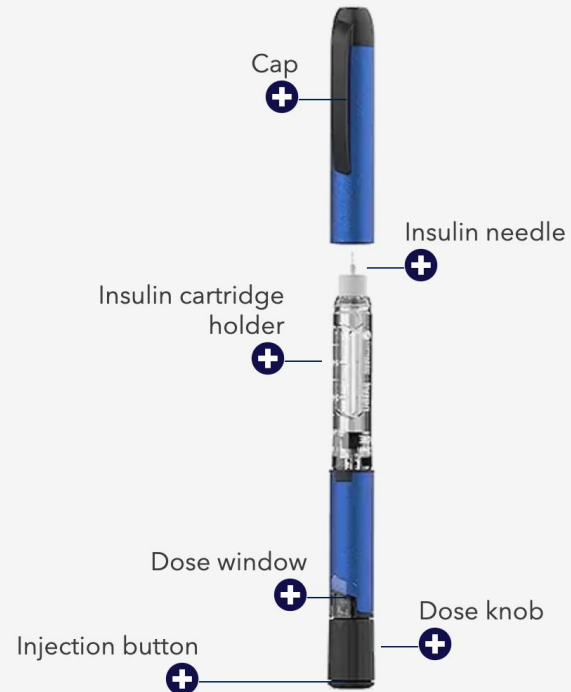
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<https://www.medtronicdiabetes.com/home>
<https://www.omnipod.com/>
<https://www.tandemdiabetes.com/>
<https://www.betabionics.com/ilet-bionic-pancreas/>

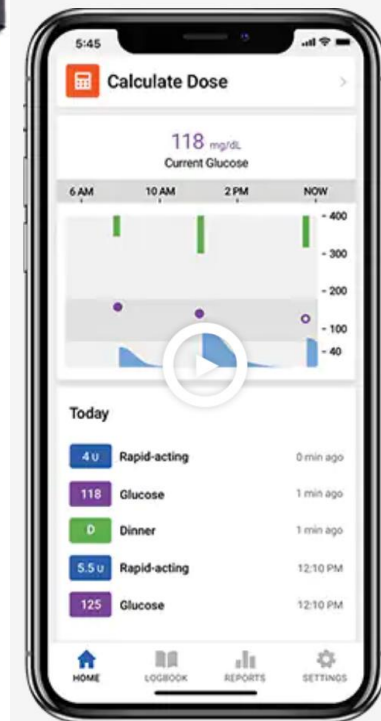
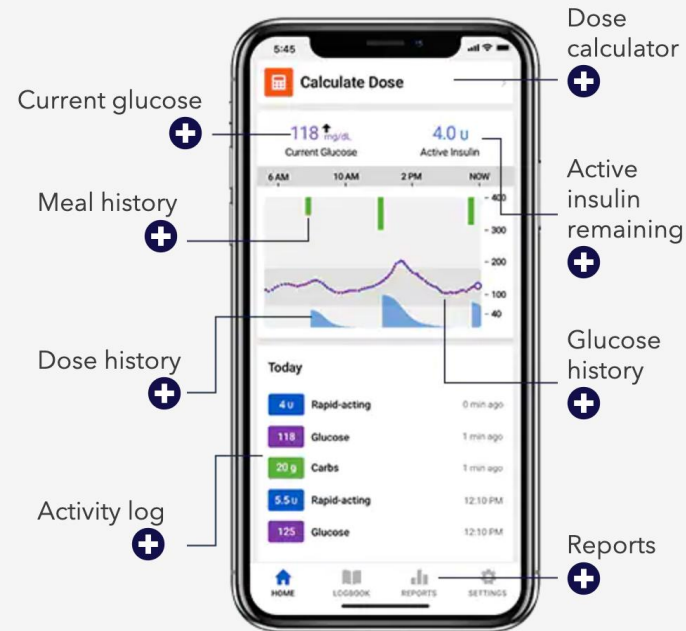


Other Insulin Delivery Devices: Smart Pen In Pen

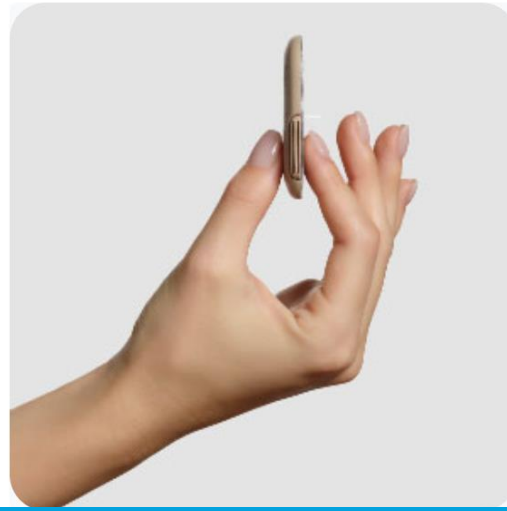
The pen



The app



Other Insulin Delivery Devices: Insulin Patch- CeQur



1 Fill the patch with a 3-day supply of insulin. CeQur Simplicity holds up to 200 units of rapid-acting insulin*



2 Use the Insertion Device to apply the patch to the abdomen for up to three days of wear and injection-free dosing

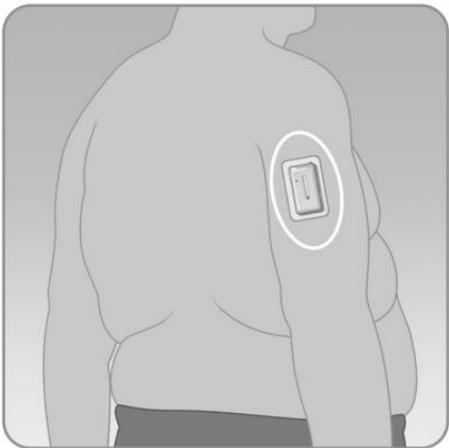
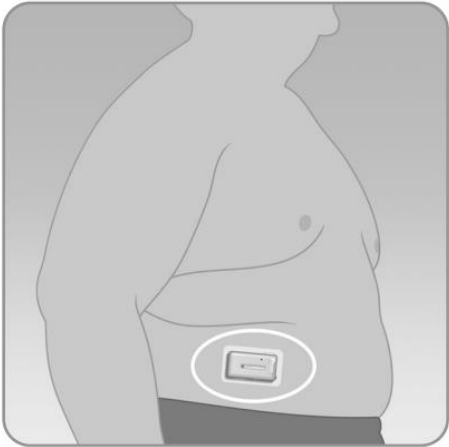


3 Remove the Insertion Device, and the patch is ready to dose.

Change every 3 days



Other Insulin Delivery Devices: Insulin Patch- V-Go



The 3 V-Go options are:

V-Go 20

- 20 Units/24 hr (0.83 U/hr) basal rate and up to 36 Units of on-demand bolus dosing in 2-Unit increments*. Total insulin volume is 56 Units.

V-Go 30

- 30 Units/24 hr (1.25 U/hr) basal rate and up to 36 Units of on-demand bolus dosing in 2-Unit increments*. Total insulin volume is 66 Units.

V-Go 40

- 40 Units/24 hr (1.67 U/hr) basal rate and up to 36 Units of on-demand bolus dosing in 2-Unit increments*. Total insulin volume is 76 Units.

*36 Units of insulin are available for on-demand bolus dosing in all V-Go options. Bolus doses are delivered in 2-Unit increments. You can only click the Bolus Delivery Button 18 times. Each click of the Bolus Delivery Button delivers 2 Units of insulin (1 click = 2 Units).



Change every 24h

<https://www.go-vgo.com/>



Case 2

57-year-old female with insulin deficient DM type 2
Diabetes complicated by mild NPDR and MAU; HbA1c 9.9%

Diabetes regimen: glargine 24 units qHS and lispro 8-10 units with meals
“Always takes insulin at bedtime, but often misses with meals as doesn’t like to inject in public”

Which of the following could help with patient’s diabetes management?

- A. Insulin pump
- B. Insulin Patch (CeQur, V-Go)
- C. Insulin pump with AID
- D. Any of the above are options for this patient



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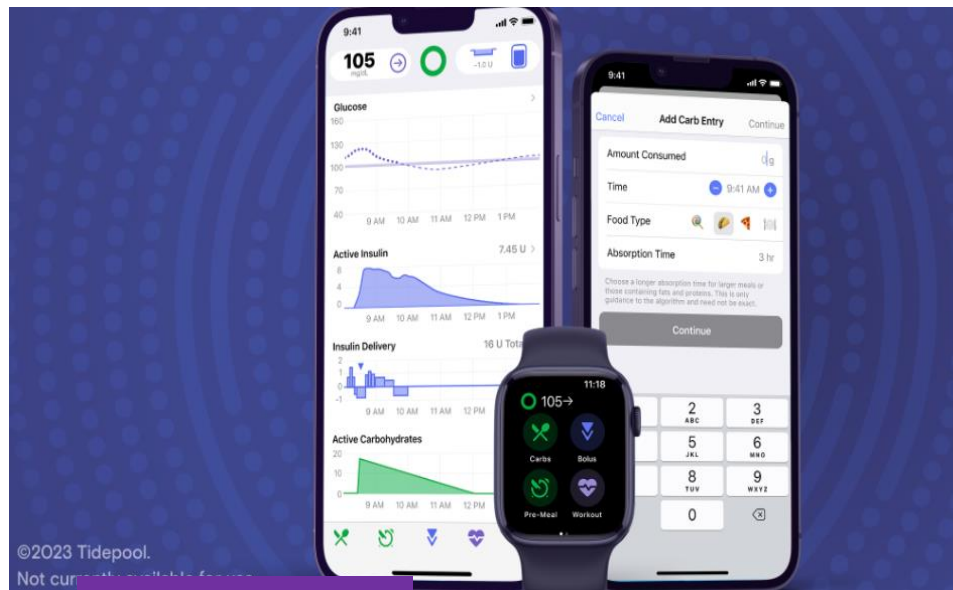
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Advances in Diabetes Technology... What's on the Horizon?

Tidepool DIY Loop (January 2023)
Automated Insulin Dosing App



Not currently available

Beta Bionics ILet (March 2023)



Twiiist



<https://www.betabionics.com/#>
<https://www.tidepool.org/tidepool-loop>
<https://www.twiiist.com/>



Which of the following patients would you consider CGM?

- A. Type 2 diabetes treated with metformin and glipizide; documented hypoglycemia**
- B. Type 1 diabetes on MDI**
- C. Cystic fibrosis related diabetes on prandial insulin**
- D. Type 3c diabetes on MDI**
- E. All of the above**



Which of the following patients would you consider CGM?

- A. Type 2 diabetes treated with metformin and glipizide; documented hypoglycemia
- B. Type 1 diabetes on MDI
- C. Cystic fibrosis related diabetes on prandial insulin
- D. Type 3c diabetes on MDI
- E. All of the above



Summary

Consider use of continuous glucose monitoring for patients with any form of diabetes and treated with insulin and/or with hypoglycemia

Utilization of insulin pump therapy or other insulin delivery devices may be helpful for patients on multiple injects of insulin per day



THANK YOU!



Questions?
Comments?



REFERENCES

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