

Advances in Diabetes Technology

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- 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

Dexcom, Inc.

Co-investigator in multisite industry-designed inpatient CGM study (study completed 11/2024)



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

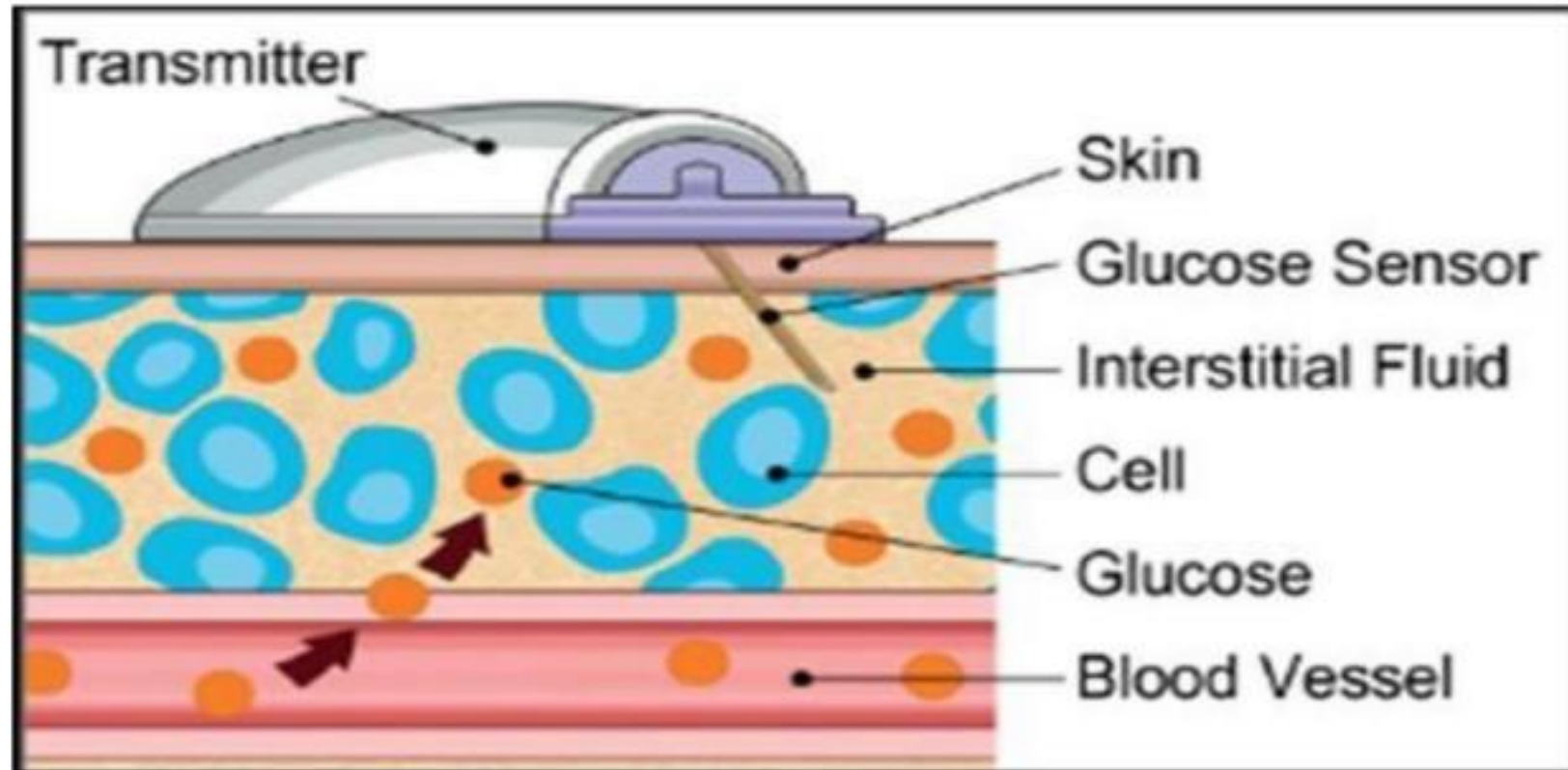
Follow-up call SMBG: 76, 52, 49*, 67, 42* mg/dL

*requiring assistance by family



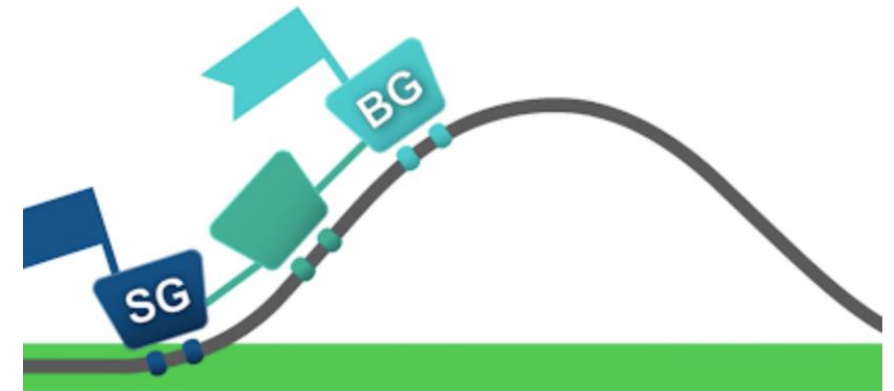
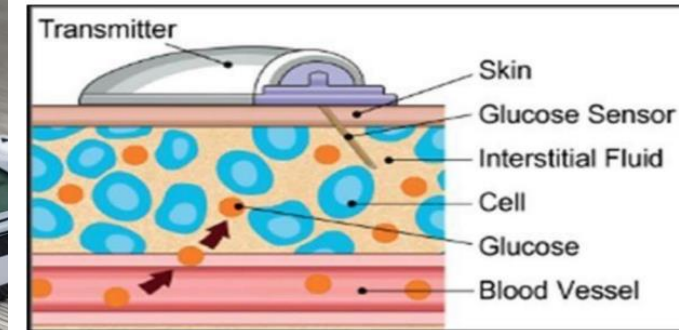
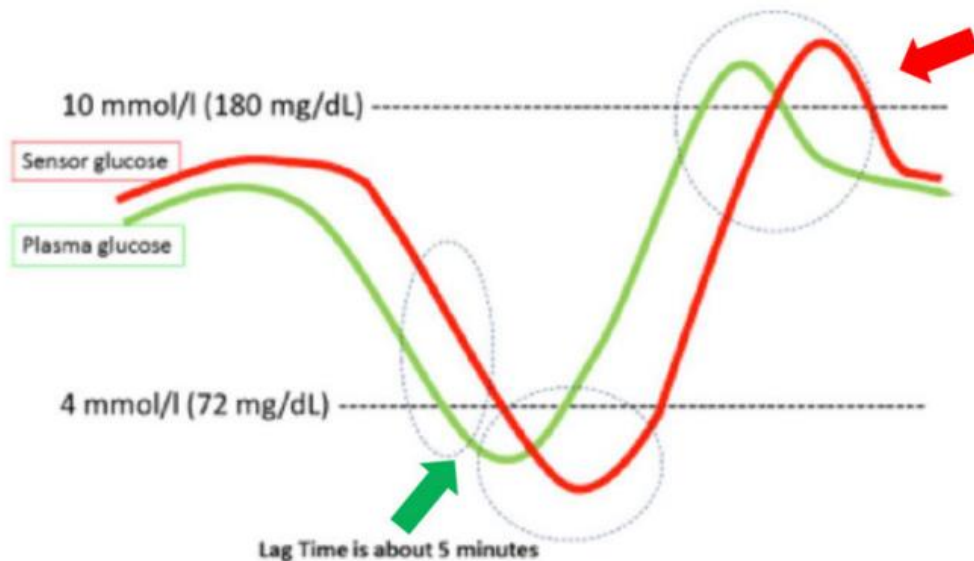
Is patient a candidate for Continuous Glucose Monitor (CGM)?

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 with 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 10-15d vs FS pending monitoring programs)



CSII: continuous subcutaneous insulin infusion

SAP: sensor augmented pump

AID: automated insulin delivery

Case 1 *Is patient a candidate for CGM?*

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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 <54 mg/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



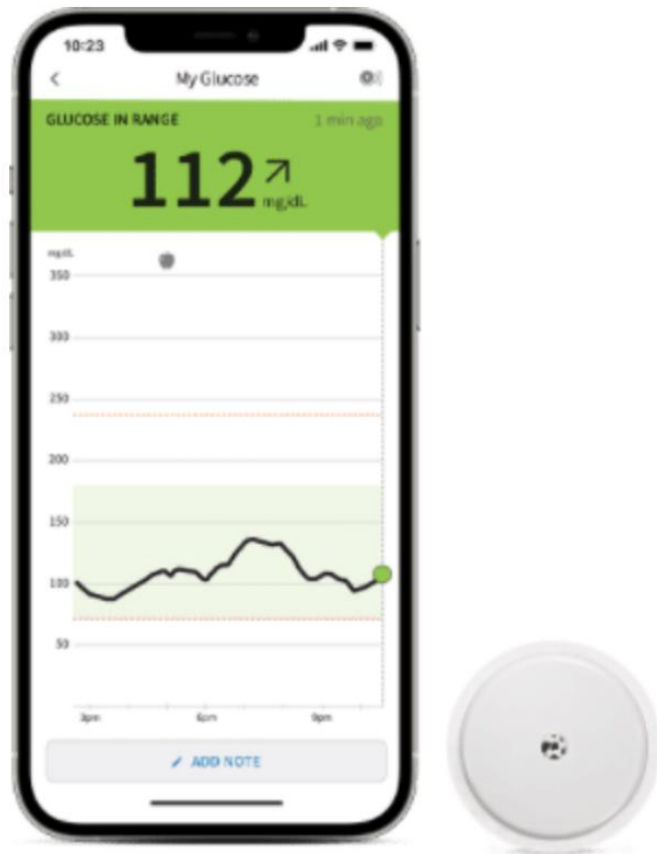
G6 production is planned to stop 7/1/26
Anticipate subsequent transition to G7 10d or G7 15d

<https://provider.dexcom.com/dexcom-cgm/what-continuous-glucose-monitoring-cgm>

Continuous Glucose Monitoring: Freestyle Libre

q14-15d

Libre 2/Libre 2 Plus



Libre 3/Libre 3 Plus



Continuous Glucose Monitoring: MiniMed



Guardian



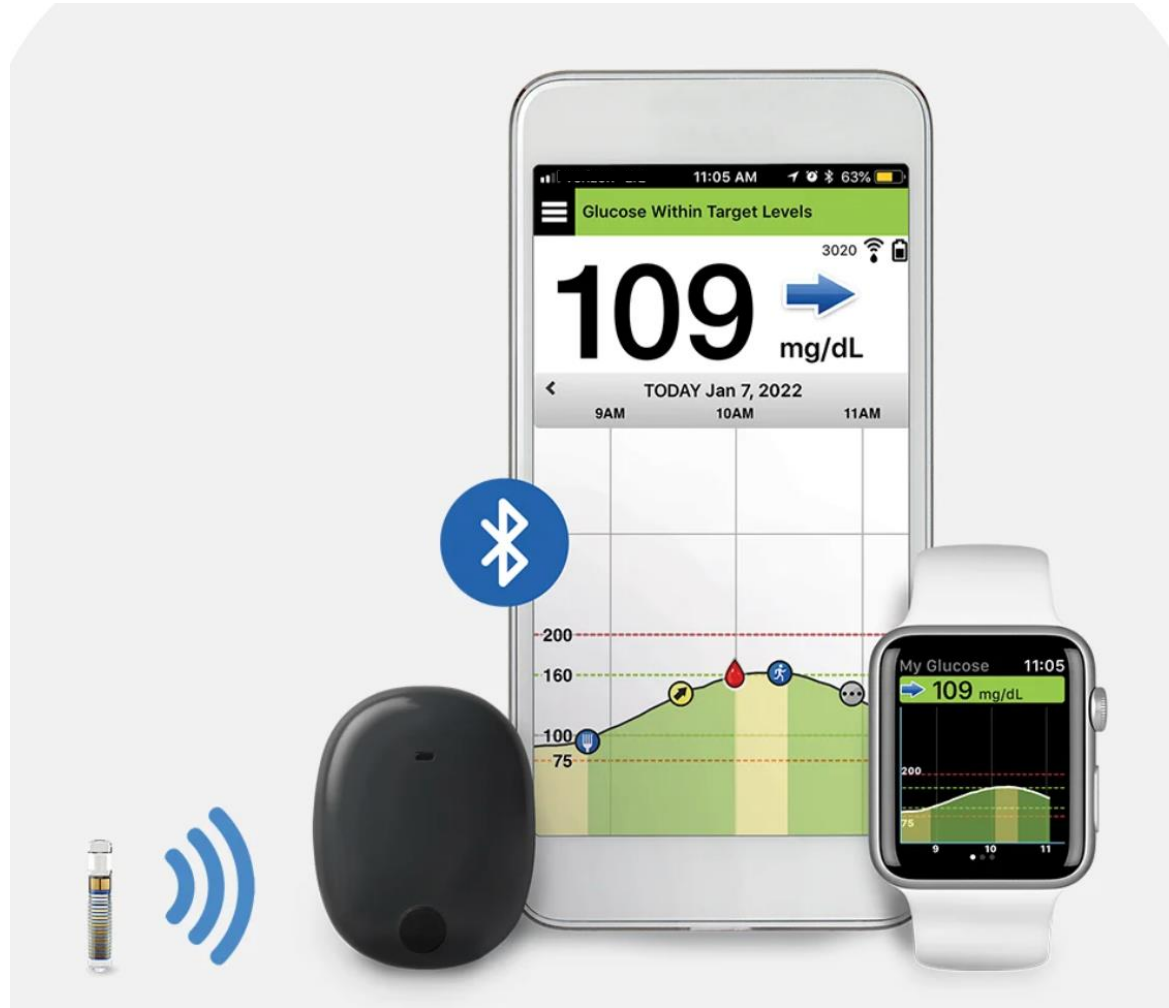
Simplera



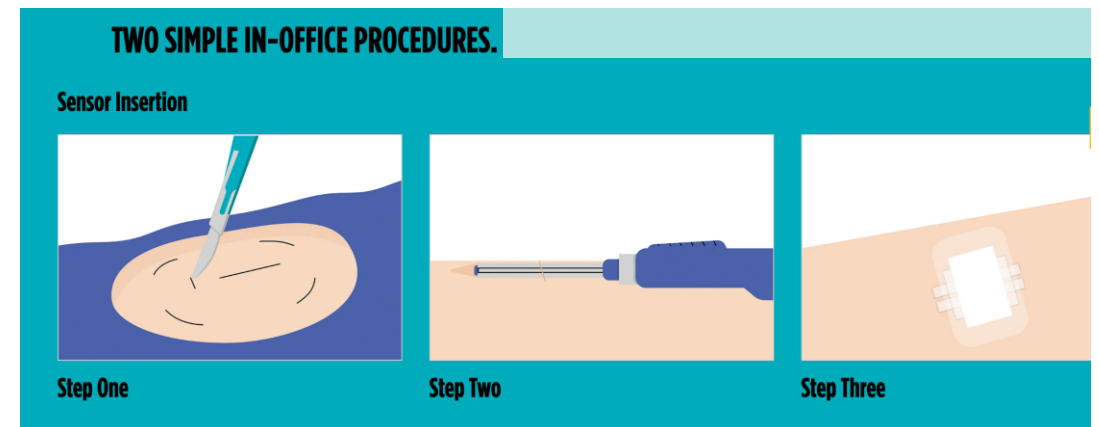
Instinct



Continuous Glucose Monitoring: Eversense



Implantable
E365 change every year



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
↑↑	↑	↑	1.7 – 2.5	Rising quickly	Give 20 % more than usual mealtime insulin
↑↑↑	↑↑		> 2.5	Rising rapidly	Give 20-30 % less than usual mealtime insulin

Insulin dose adjustments for trend arrows for various CGM devices



Continuous Glucose Monitoring: Goals and Metrics

Metric	Most Adult Patients	Older Patients/other*	Pregnant Patient ^
TAR (>250 mg/dL)	<5%	<10%	TAR >140 mg/dL:<25%
TAR (>180 mg/dL)	<25%	<50%	
TIR (70-180 mg/dL)	>70%	>50%	TIR 63-140 mg/dL:>70%
TBR (<70 mg/L)	<4%	<1%	TBR <63 mg/dL:<4%
TBR (<54 mg/dL)	<1%	<1%	TBR<54 mg/dL: <1%

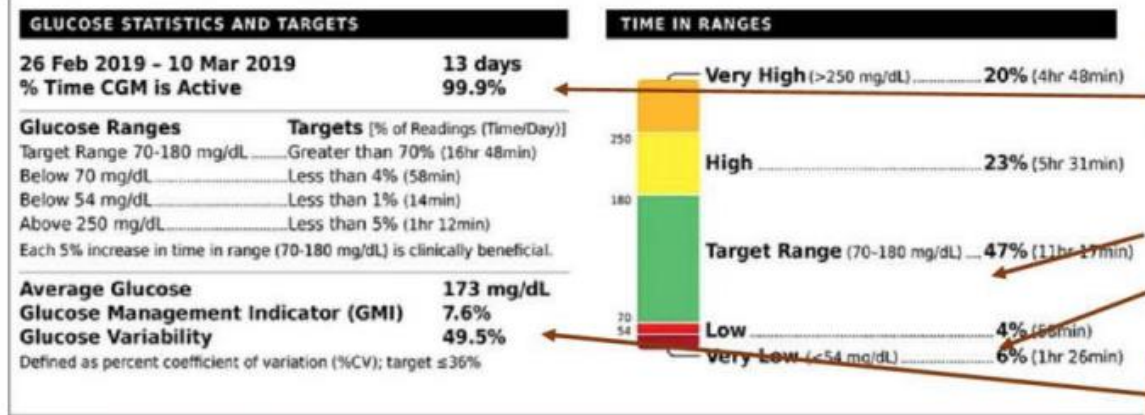
^Metrics above for women with T1D
Ongoing studies for GDM/T2D

Wear time >14d with % time CGM active >70%

*In patient with multiple comorbidities and increased risk for hypoglycemia individualized targets should be considered

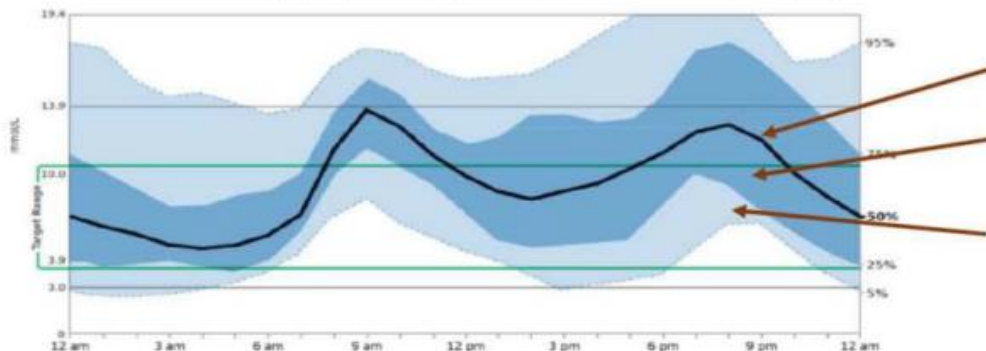
TAR: time above range
TIR: time in range
TBR: time below range



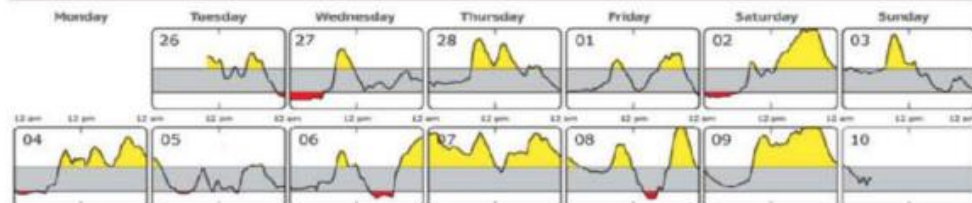


AMBULATORY GLUCOSE PROFILE (AGP)

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.

©2019 American Diabetes Association. Published online at <http://care.diabetesjournals.org/lookup/suppl/doi:10.2337/dci19-0028/-/DC1>

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

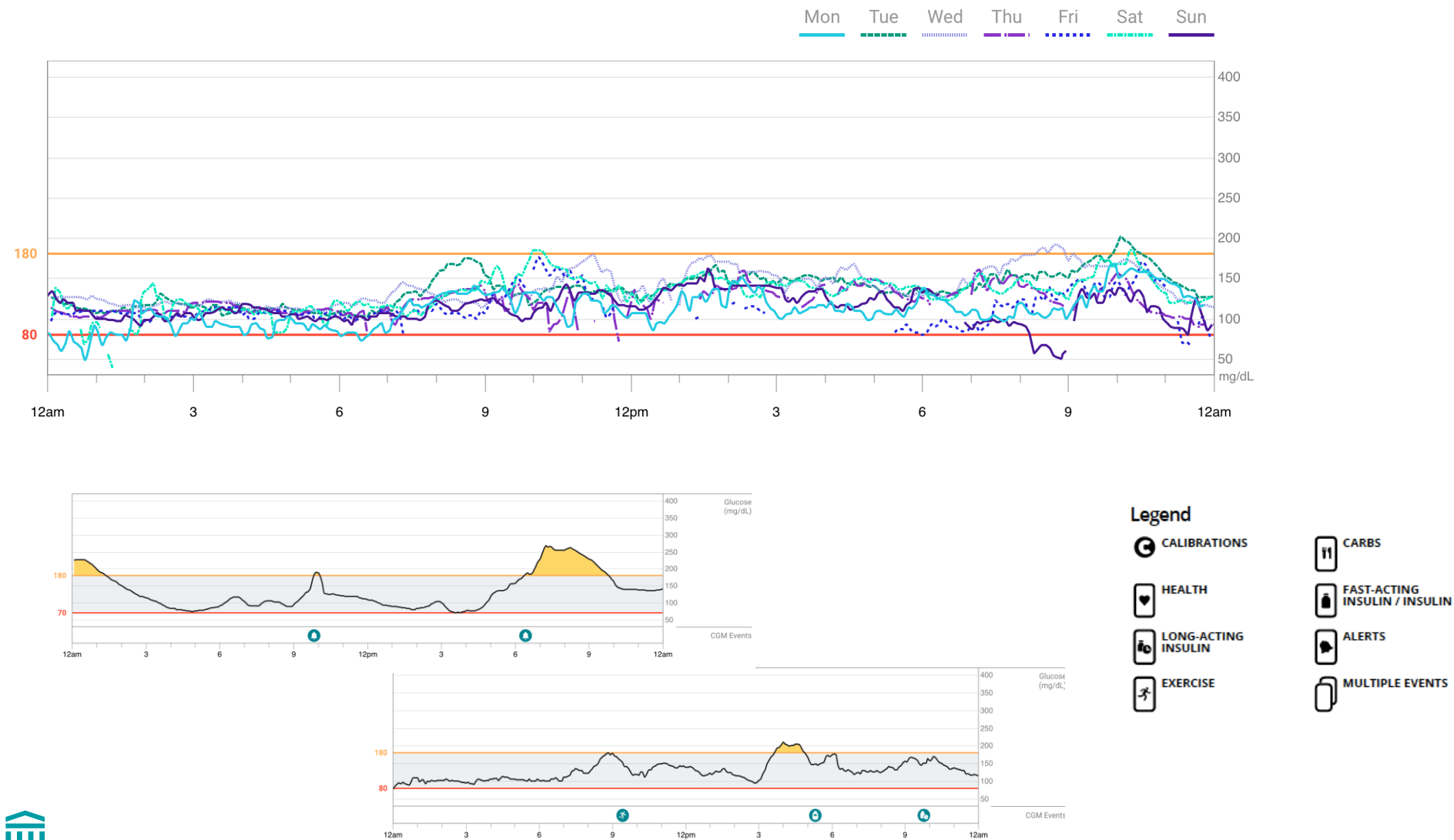
Ambulatory glucose profile: The **solid line** is the median or 50% line; half of all glucose values are above and half are below this value.
The 25th and 75th percentile curves shaded in **dark blue** represent the interquartile range or 50% of all values and are a good visual indicator of the degree 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

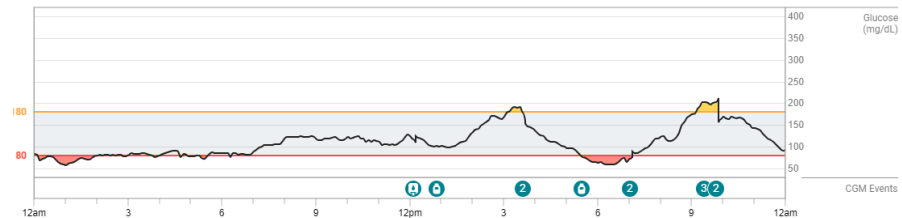
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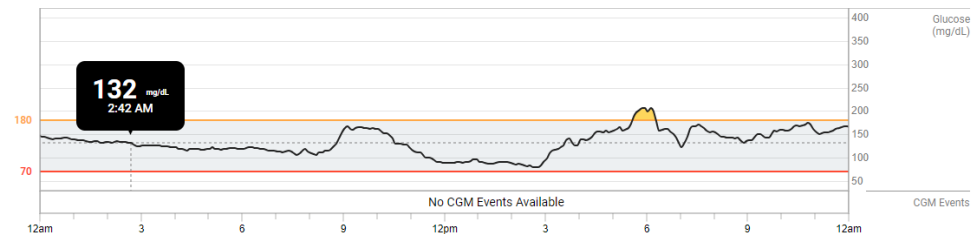
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Follow-up call SMBG: 76, 52, 49*, 67, 42* mg/dL
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Started on CGM “loves it”
glipizide and glargine adjusted
no further episodes of hypoglycemia
HbA1c 7.1 % in the subsequent 3 months



Baseline CGM



2w follow-up



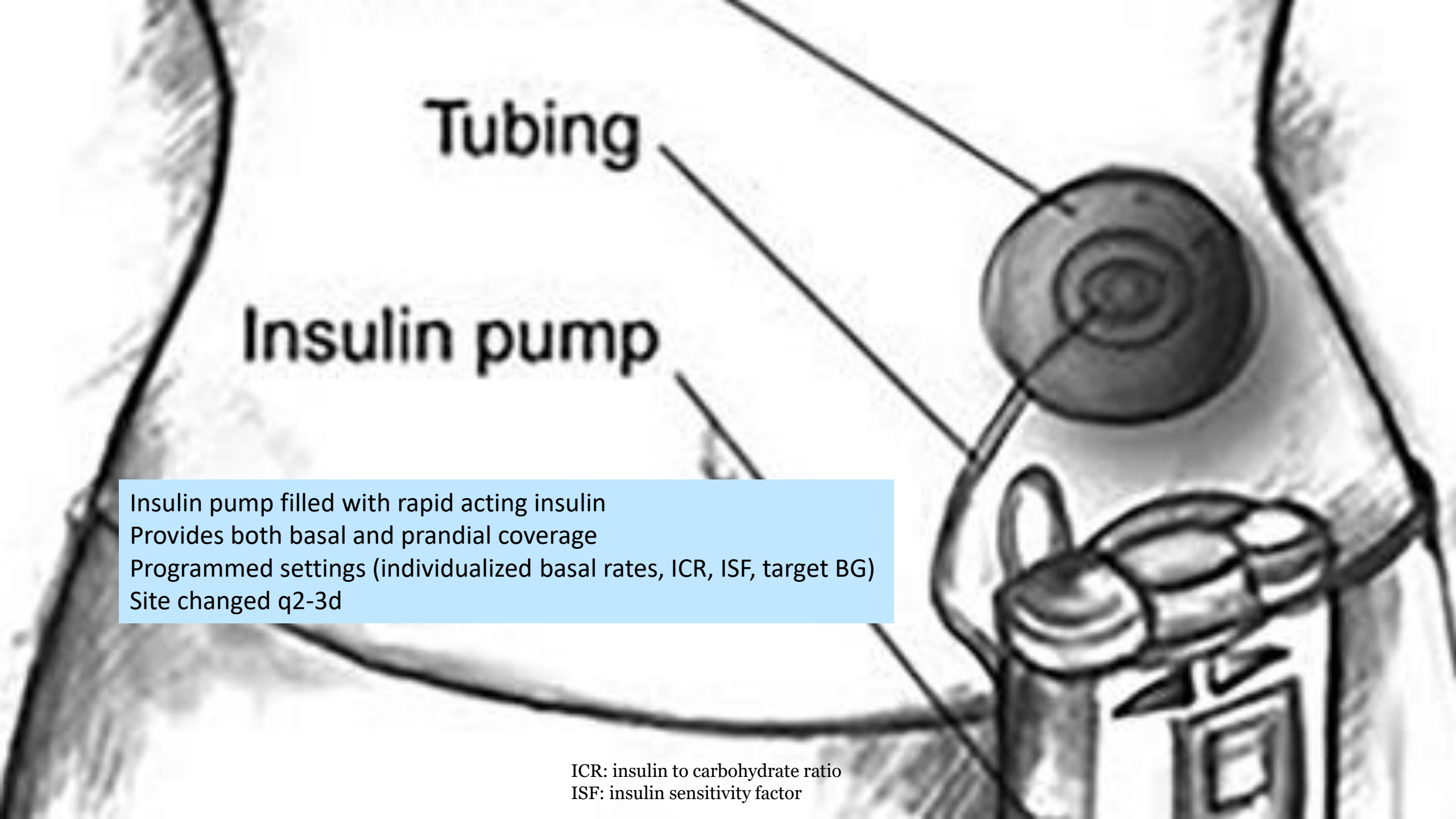
Case 2

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?





The diagram shows a person's arm with an insulin pump attached. A tube, labeled 'Tubing', connects the pump to a circular reservoir on the arm. A hand is shown holding a syringe, which is connected to the tubing. The pump itself is labeled '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

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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



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

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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?
(note: consideration for pre-set fixed dose bolus)



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..”

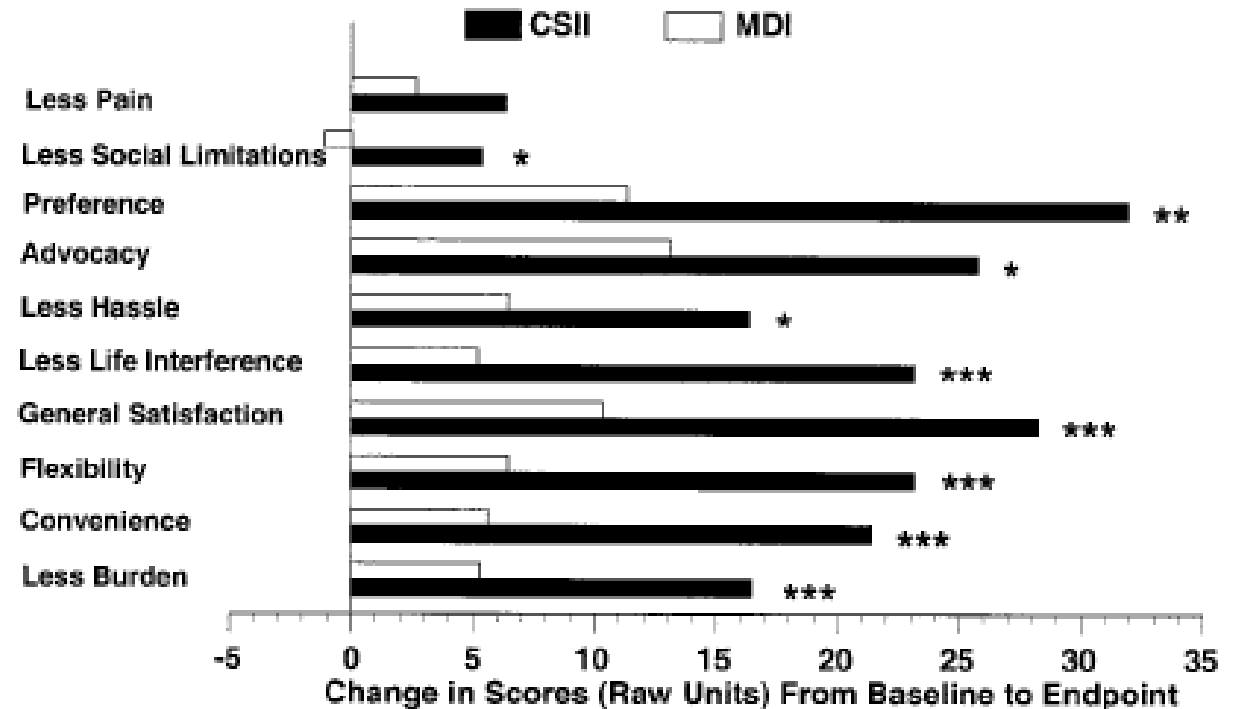
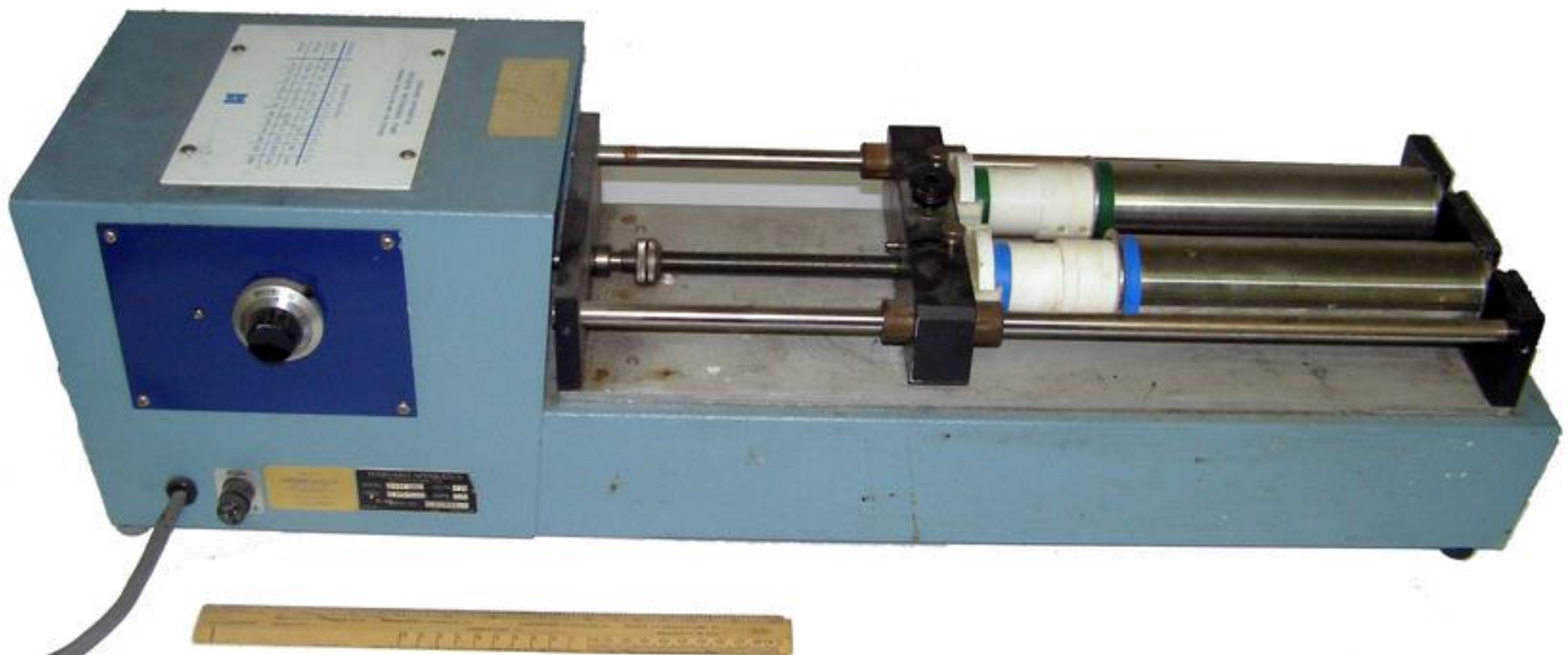


Figure 2— Change-from-baseline improvements in patient satisfaction subscores at the end of the study. Improvements were compared between treatment groups, controlling for patient age. Responses to baseline questionnaires are based on prestudy insulin treatment. Change-from-baseline scores are available 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/>

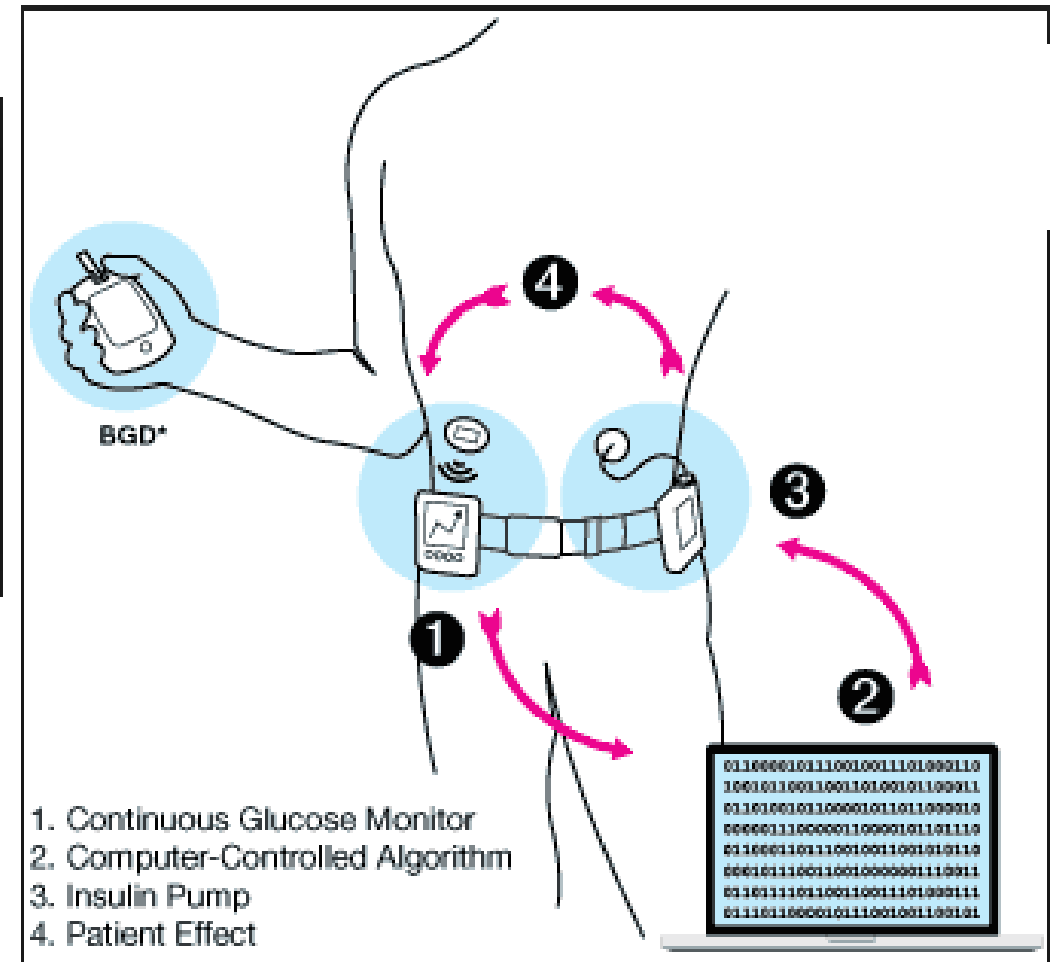
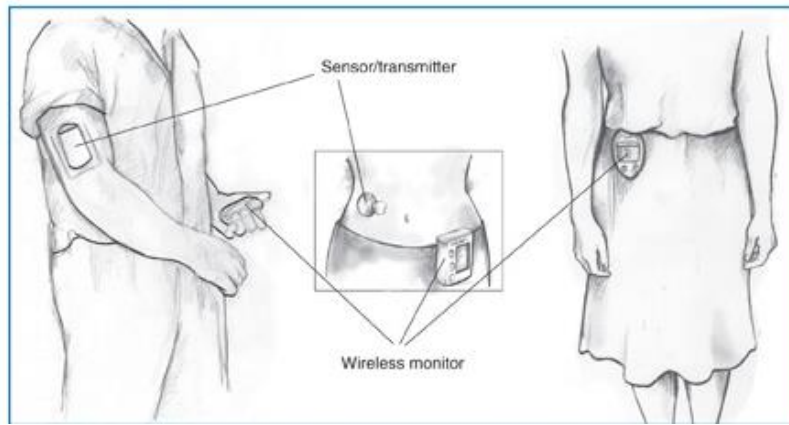
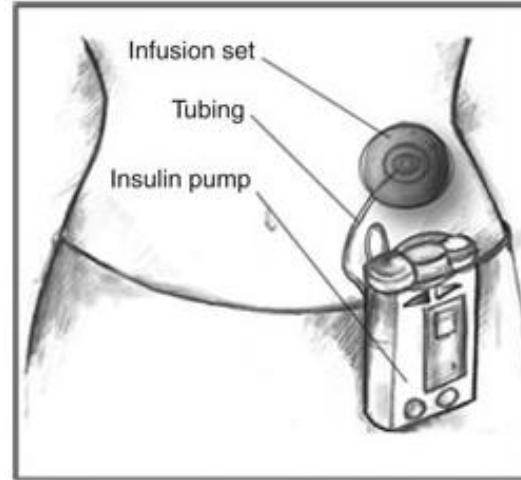
<https://www.tandemdiabetes.com/>

<https://www.twiist.com>

<https://www.betabionics.com/ilet-bionic-pancreas/>

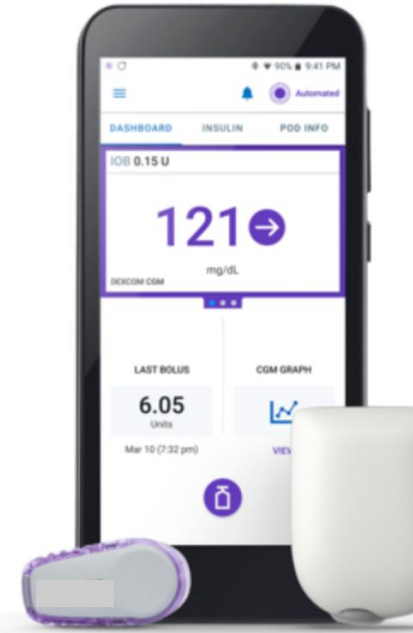
Insulin Pump and CGM

- 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



CSII: continuous subcutaneous insulin infusion
AID: automated insulin delivery

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



Additional Reference CSII with AID Systems



PANTHERprogram.org

Information is specific to use of each pump's AID features



CALCULATE				
	Basal automation?	Bolus automation?	Algorithm target glucose / target range?	Which insulin does the user give?
MiniMed™ 780G 	"Auto Basal" calculated from total daily insulin, which is updated each day at midnight. Auto Basal is adjusted every 5 min based on recent CGM glucose trends, aiming for the target glucose value.	Auto correction boluses (max. every 5 min) if glucose is > 120 mg/dL. Auto corrections can be turned on or off.	3 Target options: 100, 110, 120 mg/dL User can set 1 target for 24 hr. period	User gives boluses for meals by entering total grams of carbs in the bolus menu.
t:slim X2™ & Mobi 	Adjusts the programmed basal rates every 5 minutes based on a 30 min prediction of CGM glucose, aiming for the target glucose range.	Auto correction boluses (max once/hr) if glucose is predicted to be >180 mg/dL in 30 min.	Target range: 112.5-180 mg/dL	User gives boluses for meals by entering total grams of carbs in the bolus menu. User can deliver correction boluses as needed.
Omnipod® 5 	"Adaptive Basal" calculated from total daily insulin, which is updated at each Pod change. Adaptive Basal is adjusted every 5 min based on a 60 min prediction of CGM glucose, aiming for the target glucose value.	No automated boluses. Algorithm will increase basal doses up to 400% of the adaptive basal rate to help correct hyperglycemia.	5 target options: 110, 120, 130, 140, 150 mg/dL Can set multiple target settings throughout 24 hr period	User gives boluses for meals by entering total grams of carbs in the bolus menu. User can deliver correction boluses as needed.
twiist™ 	Adjusts the programmed basal rates every 5 minutes based on a 6-hour predicted CGM glucose, aiming for the correction target (middle of correction range).	No automated boluses. Algorithm will increase basal doses up to the max basal rate programmed in the pump to help correct hyperglycemia.	Target range (called "Correction Range"), can set any range between 87-180 mg/dL. Algorithm targets middle of the range. Can set multiple ranges throughout 24 hour day.	User gives boluses for meals by entering total grams of carbs in the bolus menu. User can deliver correction boluses as needed.
iLet Bionic Pancreas 	Insulin Automation is initialized by entering user's weight. Basal insulin delivery adjusts every 5 minutes based on CGM glucose trends and adapts over time based on the iLet's analysis of the user's daily glucose patterns.	All meal bolus doses and correction bolus doses are automated. Auto correction boluses max. every 5 minutes as needed if glucose > CGM target setting.	3 target options: Usual (120 mg/dL), Lower (110 mg/dL), Higher (130 mg/dL) Can set up to 2 target settings per 24 hr period	User completes a meal "announcement" to prompt the iLet to deliver a meal bolus, which involves estimating the carbohydrate amount for each meal ("Usual for Me"/ "More" than usual /"Less" than usual).

CALCULATE				
	Basal automation?	Bolus automation?	Algorithm target glucose / target range?	Which insulin does the user give?

ADJUST						
When using AID:	Can you adjust basal rates?	Can you adjust I:C ratios?	Can you adjust correction factor (sensitivity)?	Can you adjust active insulin time?	What are the special features in automated insulin delivery?	Which pump settings impact automated insulin delivery (insulin delivered by the algorithm)?

REVERT		
Is there a limited automation mode the system may revert to if there is a loss of CGM communication or other reasons?	When will the system automatically revert to manual mode (conventional pump therapy using programmed basal rates — no insulin dose automation)?	

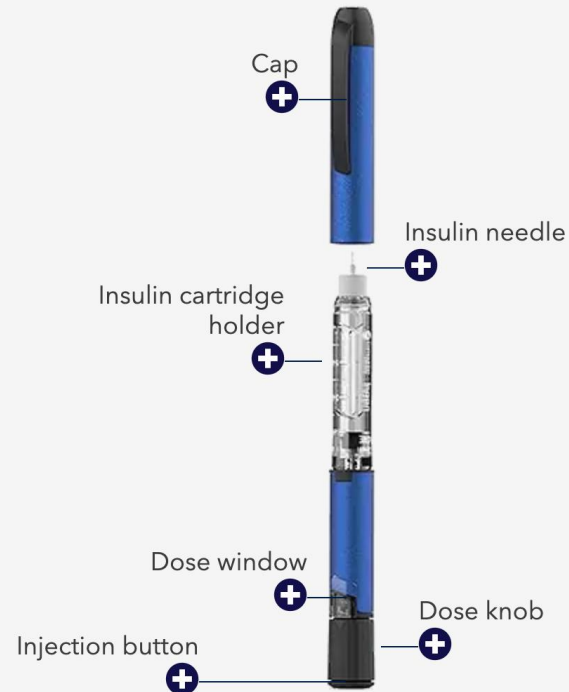
EDUCATE

SENSOR/SHARE			
Which CGM is compatible? *CGM options may vary by region	Can user see real-time data on personal cell phone?	Can others see data remotely?	Is data automatically stored in the cloud?

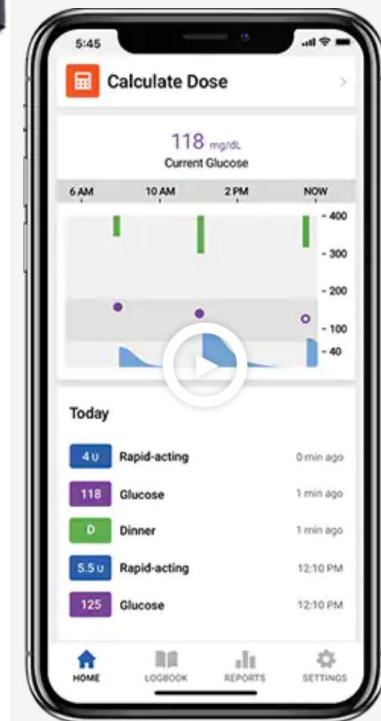
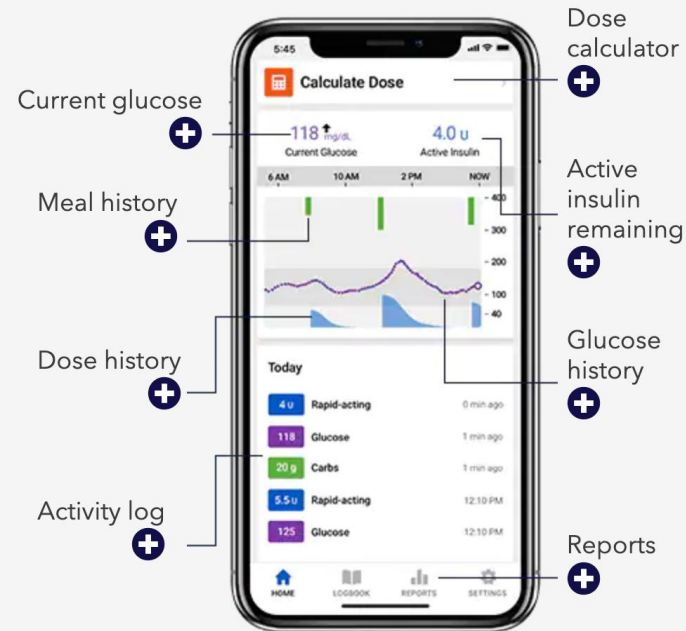


Other Insulin Delivery Devices: Smart Pen In Pen

The pen



The app

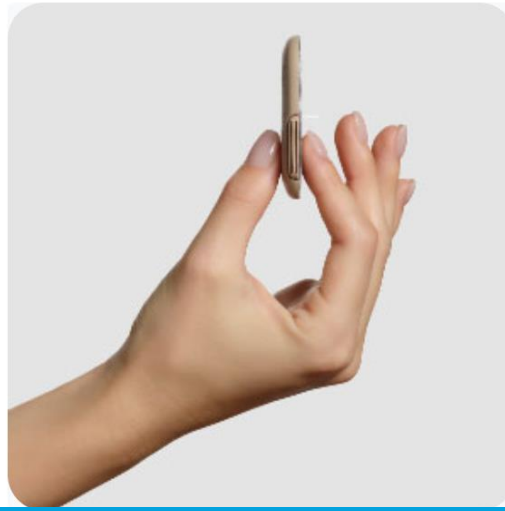


Other Insulin Delivery Devices: Smart MDI

Smart Pen + CGM



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 Inserter to apply the patch to the abdomen for up to three days of wear and injection-free dosing

3

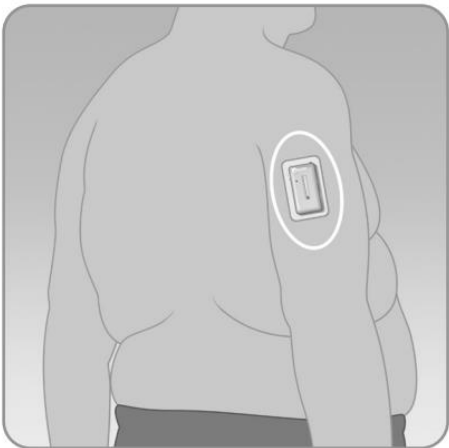
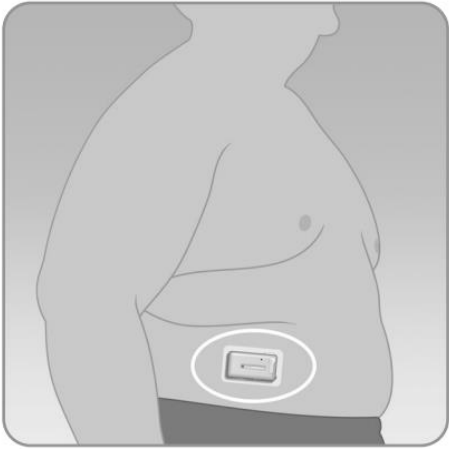


Remove the Inserter, and the patch is ready to dose.

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



Case 2

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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**



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?

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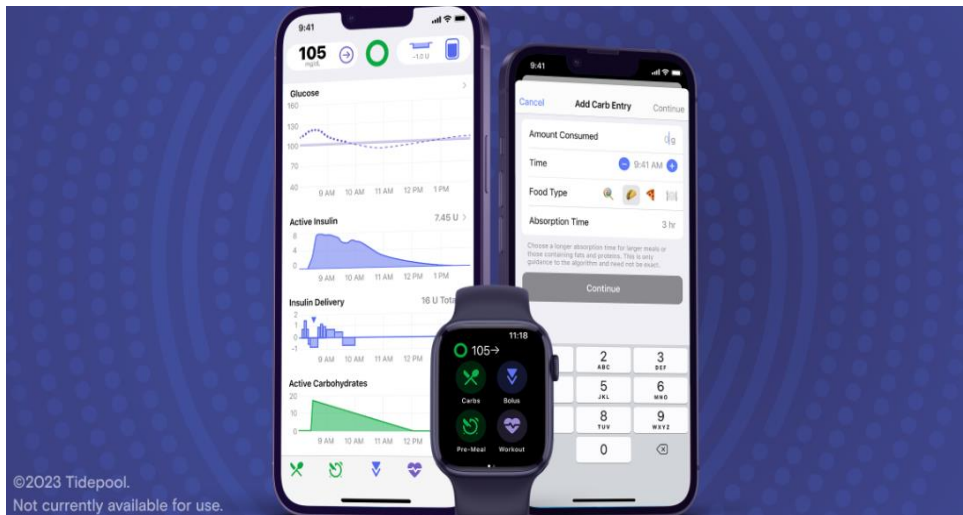


Advances in Technology... What's on the Horizon?

Tidepool DIY Loop (January 2023)
Automated Insulin Dosing App

Beta Bionics ILet
(March 2023: insulin only
Bi-hormonal system not yet available)

CSII with AID in Pregnancy
Tandem CIQ
(approved April 27, 2026)



Not currently available



CGM OTC: Libre Rio (2024)

**OTC Glucose biosensors*
Stelo (March 2024)
Lingo (June 2024)

**patients without DM*



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 injections of insulin per day



THANK YOU!



Questions?
Comments?



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