Brigham and Women's Hospital
Founding Member, Mass General Brigham

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%

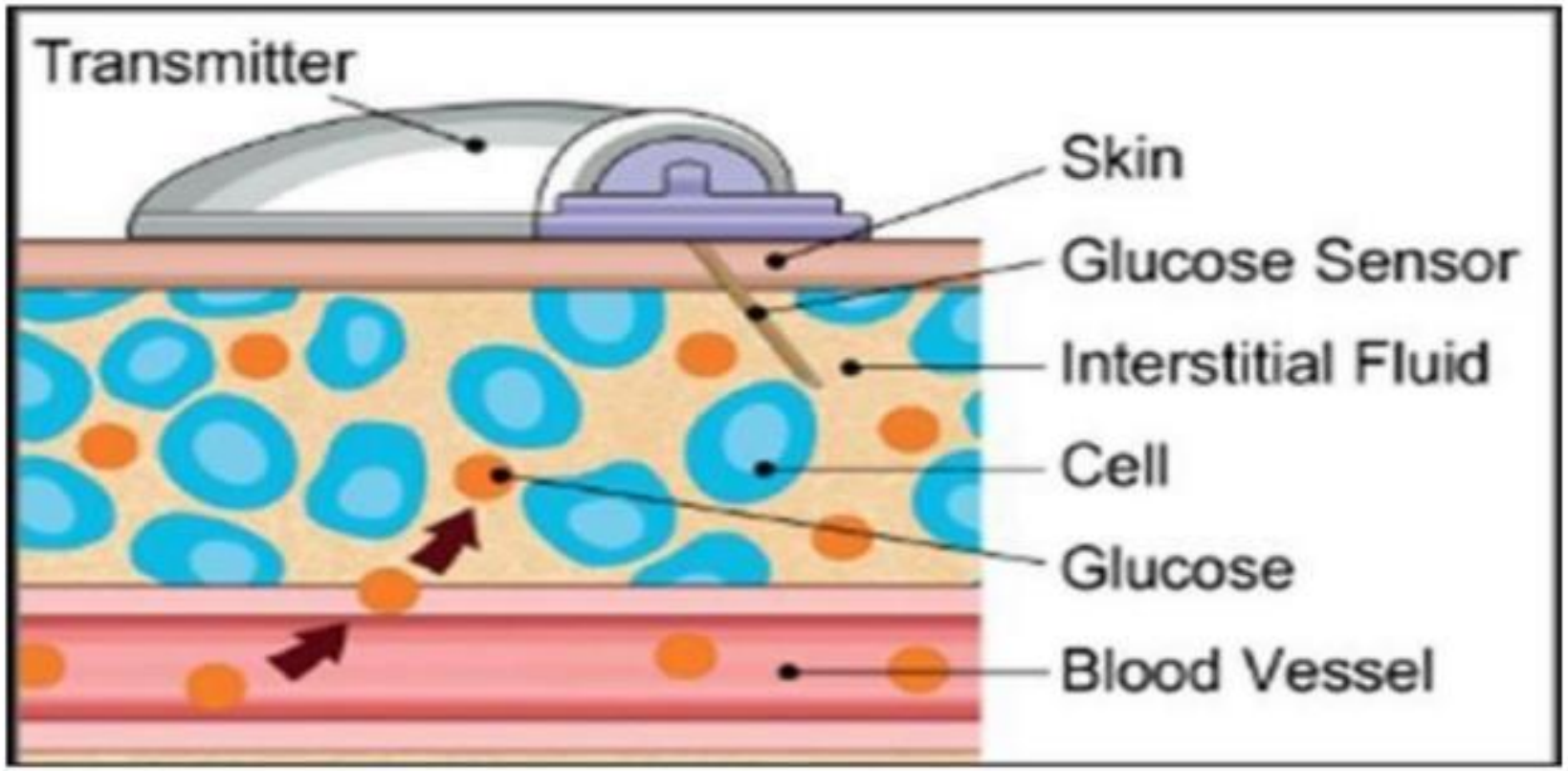
Routine visit: family member shares patient complaints of headaches
"light-headed" "dizzy"- early morning, late afternoon, bedtime
symptoms often improve after eating

During visit suggested FSBG monitoring, especially when having symptoms
Follow-up call SMBG: 76, 52, 49*, 67 ,42* mg/dL

*requiring assistance by family

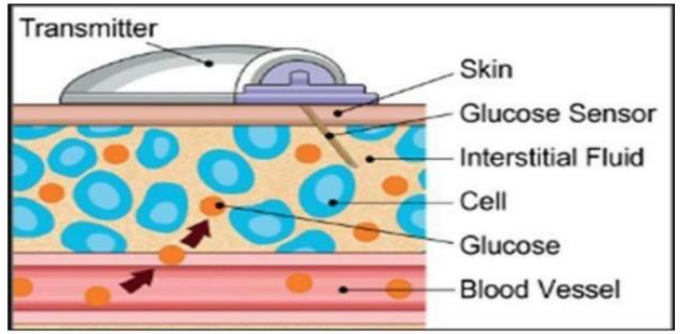
Is patient a candidate for Continuous Glucose Monitor (CGM)?

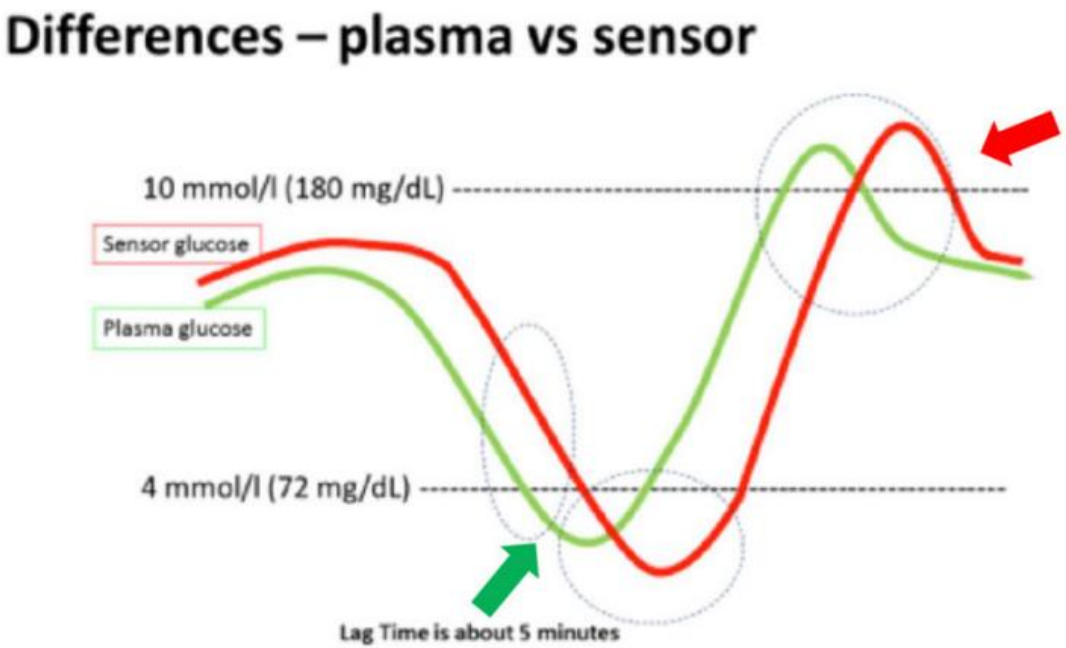
What is continuous glucose monitoring (CGM)?

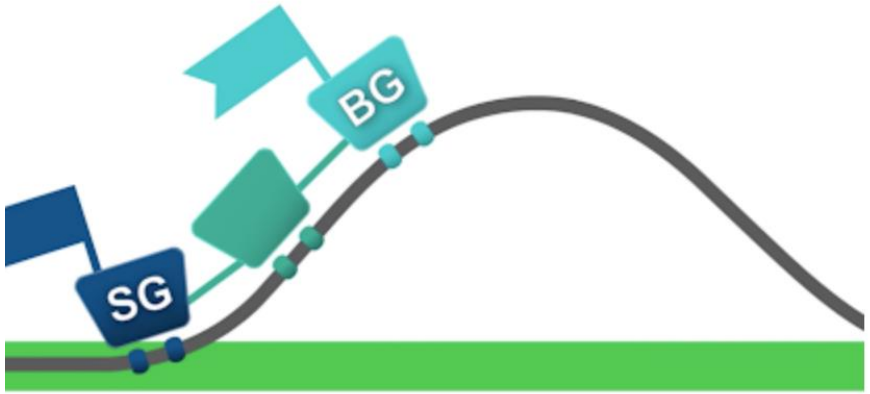


Soni A et al . Arch Dis Child Educ Pract Ed. 2022 Jun;107(3):188-193.

CGM: Is this the same as fingerstick glucose monitoring?







Soni A, et al. Arch Dis Child Educ Pract Ed 2022;107:188–193
https://education.steady.health/hc/en-us/articles/360052232533
https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetesn
a

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?*

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%

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

https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52464

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.

https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52464

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

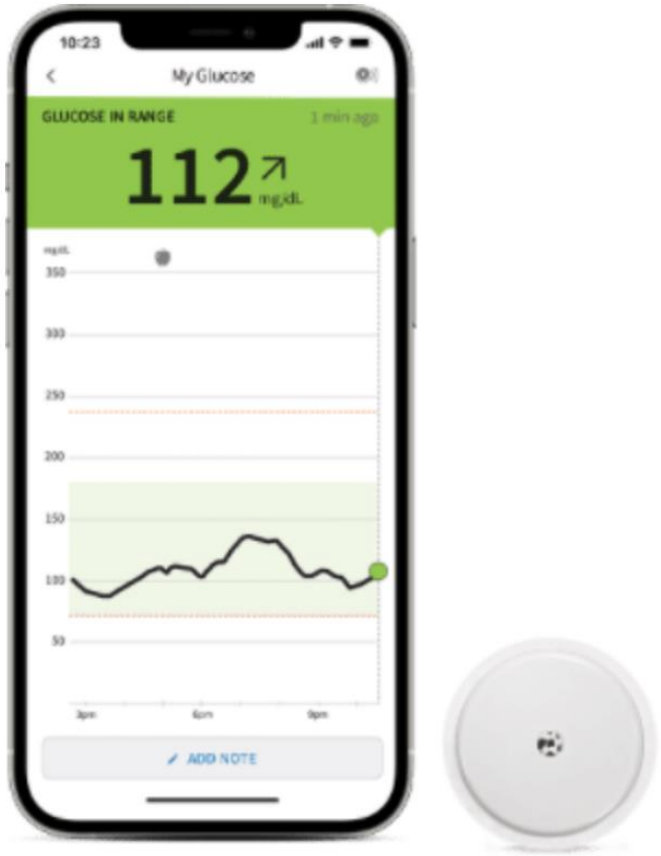
G6 production is planned to stop 7/1/26
Anticipate subsequent transition to G7 10d or G7 15d

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

https://www.freestyle.abbott/eu-en/products/freestyle-libre-3.html

Continuous Glucose Monitoring: MiniMed

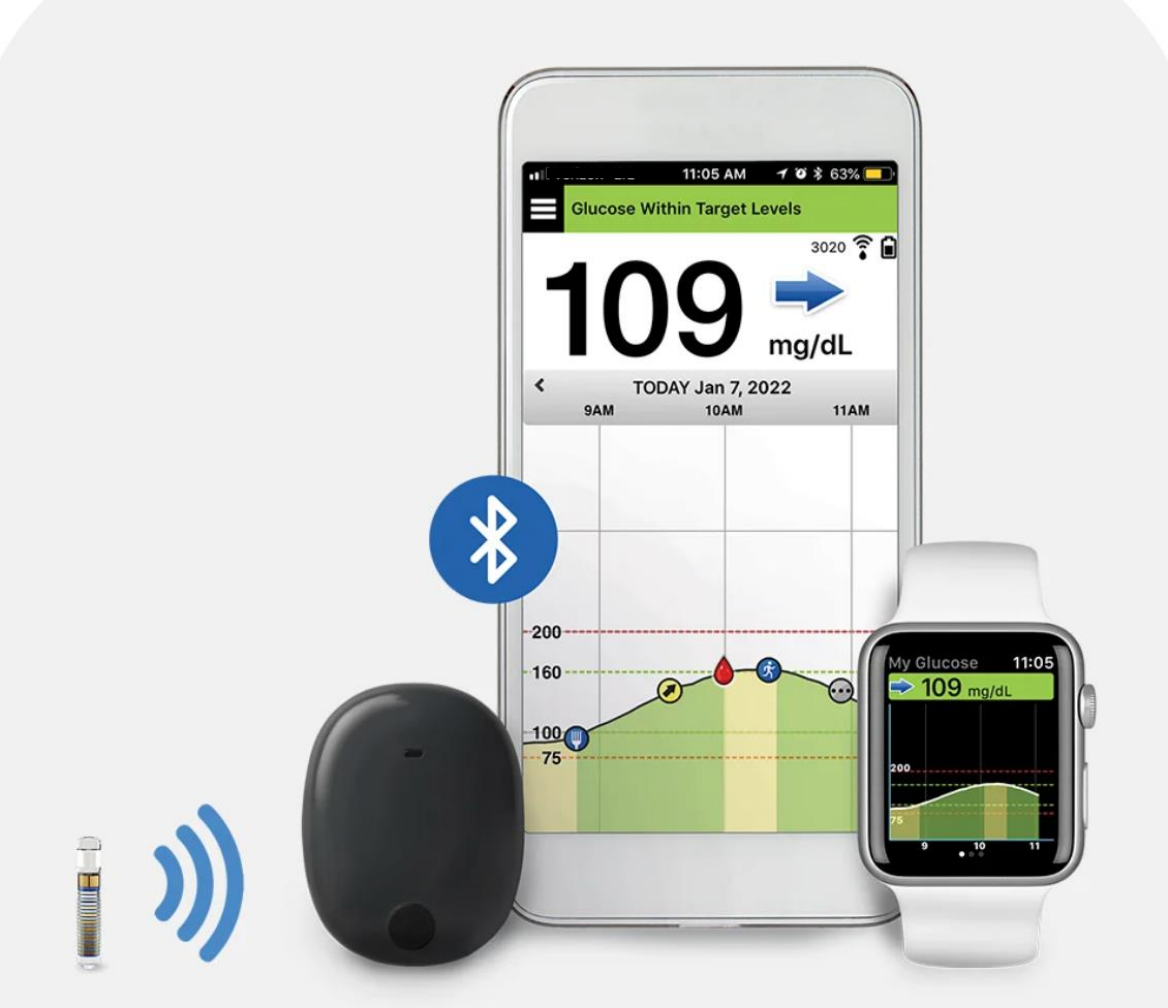
Guardian

Simplera

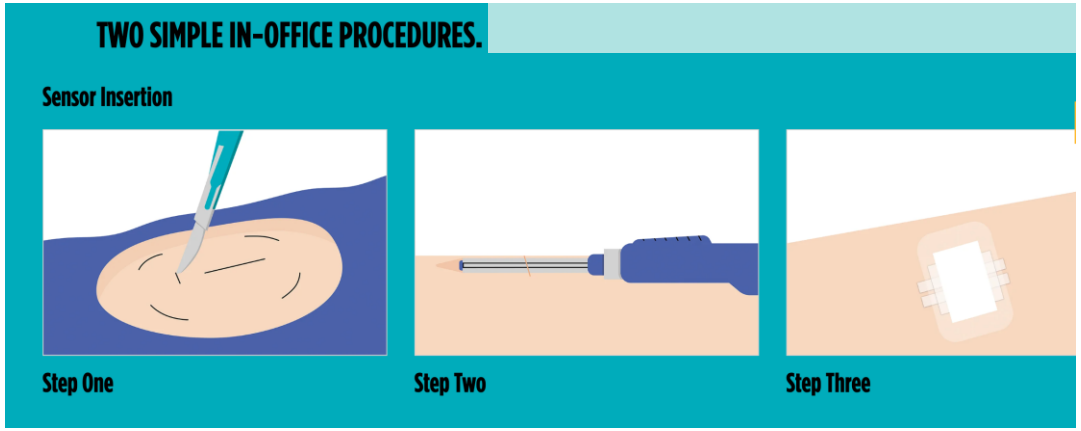
Instinct

https://www.medtronic.com/en-ca/diabetes/support/product-support/cgm-sensors.htm
https://www.minimed.com/en-us/support/product-support/sensors/compare-sensorsl

Continuous Glucose Monitoring: Eversense



Implantable
E365 change every year



https://www.ascensiadiabetes.com/eversense/eversense-cgm-system/sensor
https://www.eversensecgm.com//

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

Soni A, et al. Arch Dis Child Educ Pract Ed 2022;107:188-193.

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%

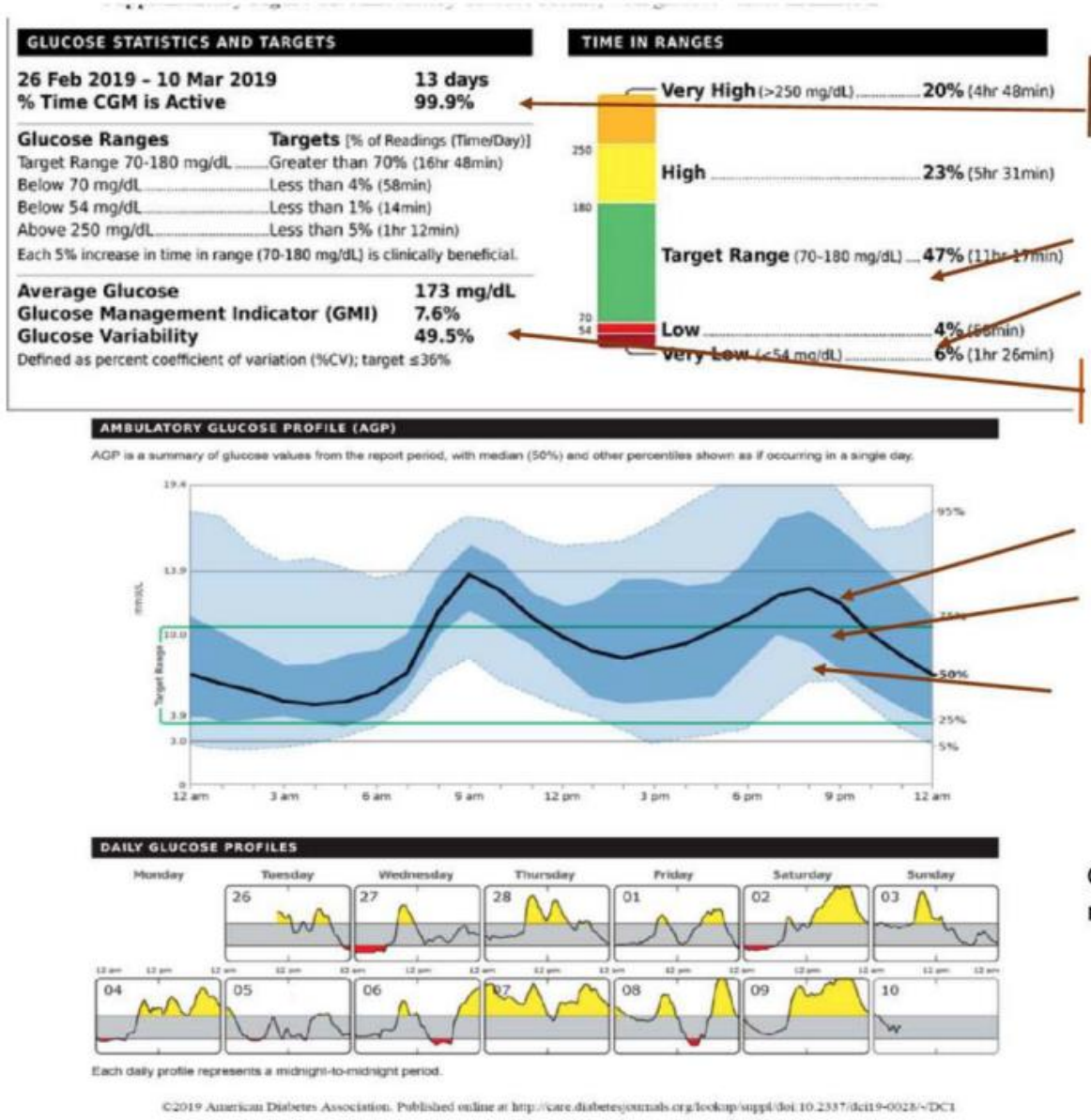
^Metrics above for women with TID
Ongoing studies for GDM/T2D

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

ADA Standards of Care in Diabetes—2026. *Diabetes Care* 1 January 2026
AAACE Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus. Endocr Pract. 2021 Jun;27(6):505-537..



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%

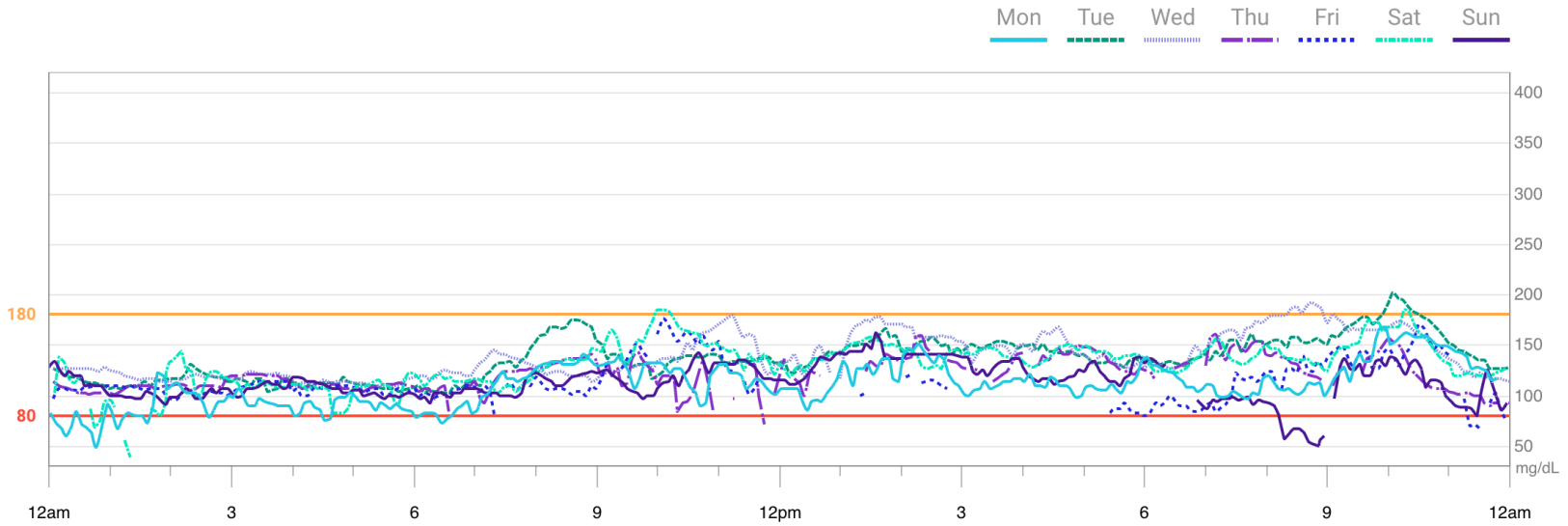
Glucose Management Indicator (GMI)- Provides with estimated HbA1c
Glucose variability (GV)- refers to how much the glucose readings varies from mean or median glucose. Low GV indicates stable glucose profile

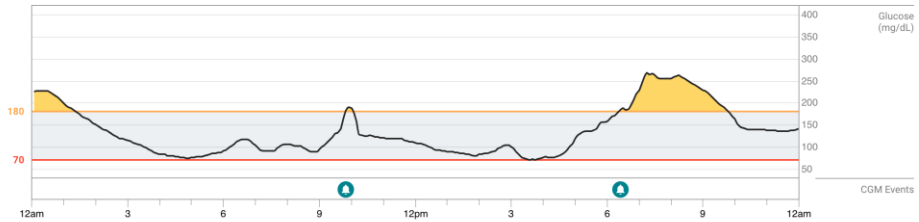
Ambulatory glucose profile: The **solid line** is the median or 50% line; half of all glucose values are above and half are below this value.
The 25th and 75th percentile curves shaded in **dark blue** represent the interquartile range or 50% of all values and are a good visual indicator of the degree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

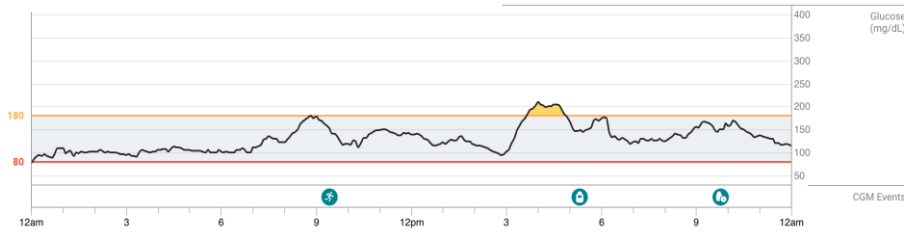
Graph showing daily data. Each daily profile represents midnight to midnight data

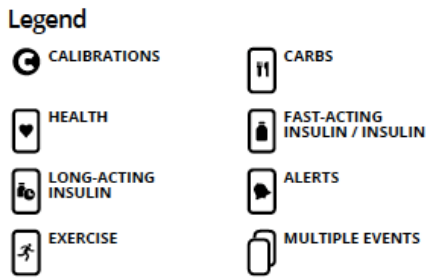
Figure 4 Example of an AGP (ambulatory glucose profile).

Cloud based data remote glucose monitoring









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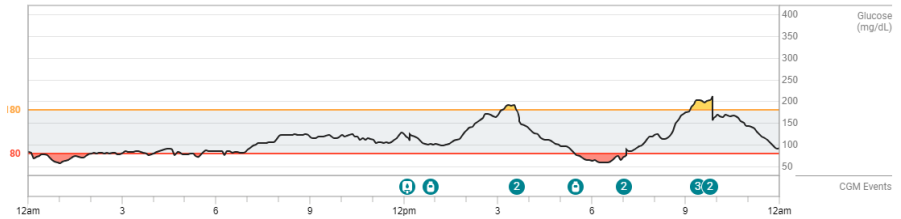
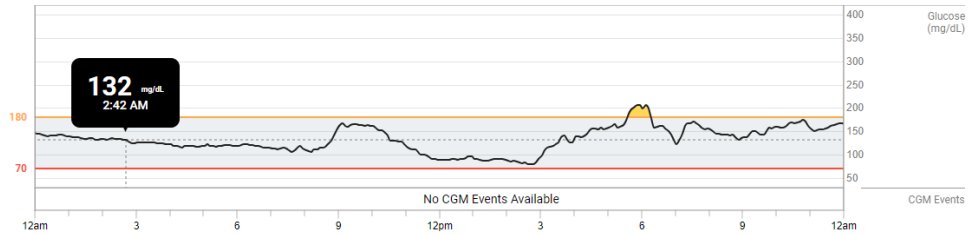


Baseline CGM



2w follow-up

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

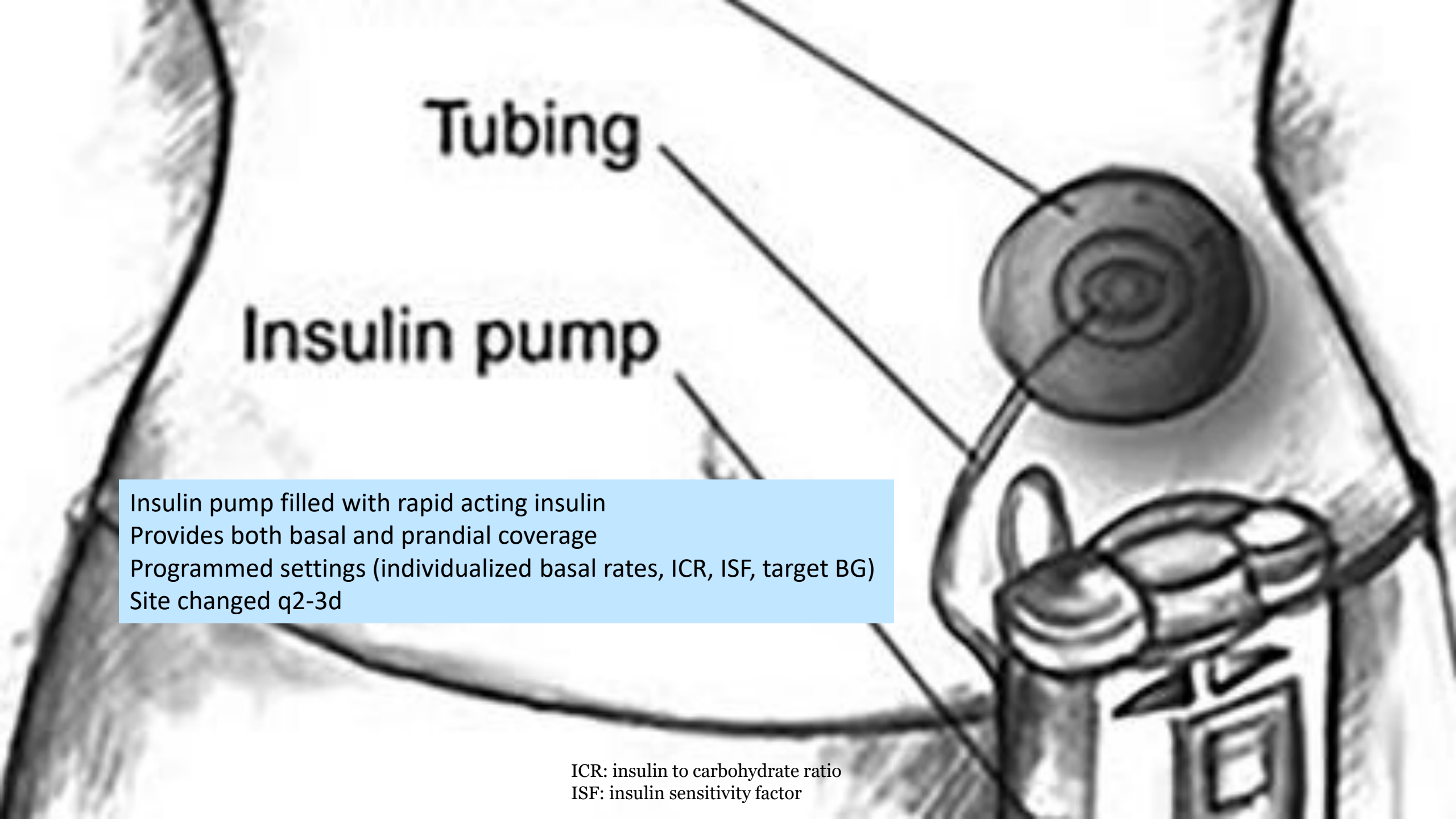
Case 2

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?

NPDR: non-proliferative diabetic retinopathy
MAU: microalbuminuria



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

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A. Yes
B. No

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A. Yes
B. No

NPDR: non-proliferative diabetic retinopathy
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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)

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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.."

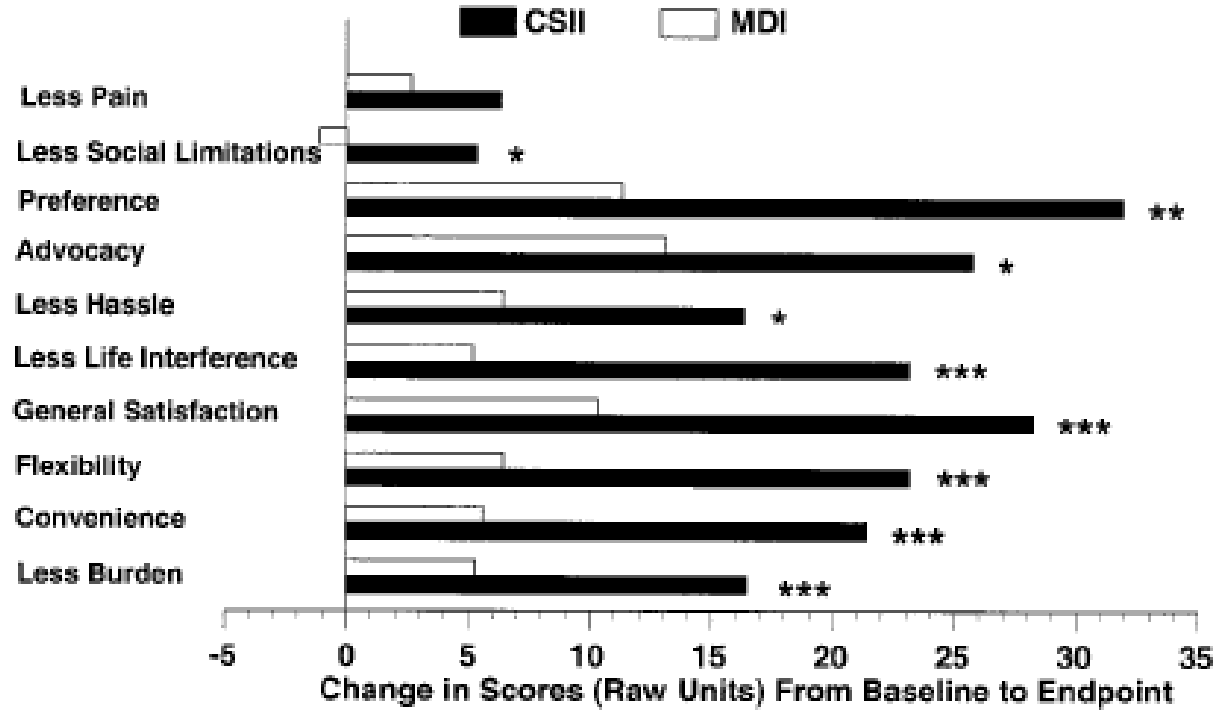

Figure 2— *Change-from-baseline improvements in patient satisfaction subscores at the end of the study. Improvements were compared between treatment groups, controlling for patient age. Responses to baseline questionnaires are based on prestudy insulin treatment. Change-from-baseline scores are available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

Raskin P et al. Diabetes Car.e 2003 Sep;26(9):2598-603.

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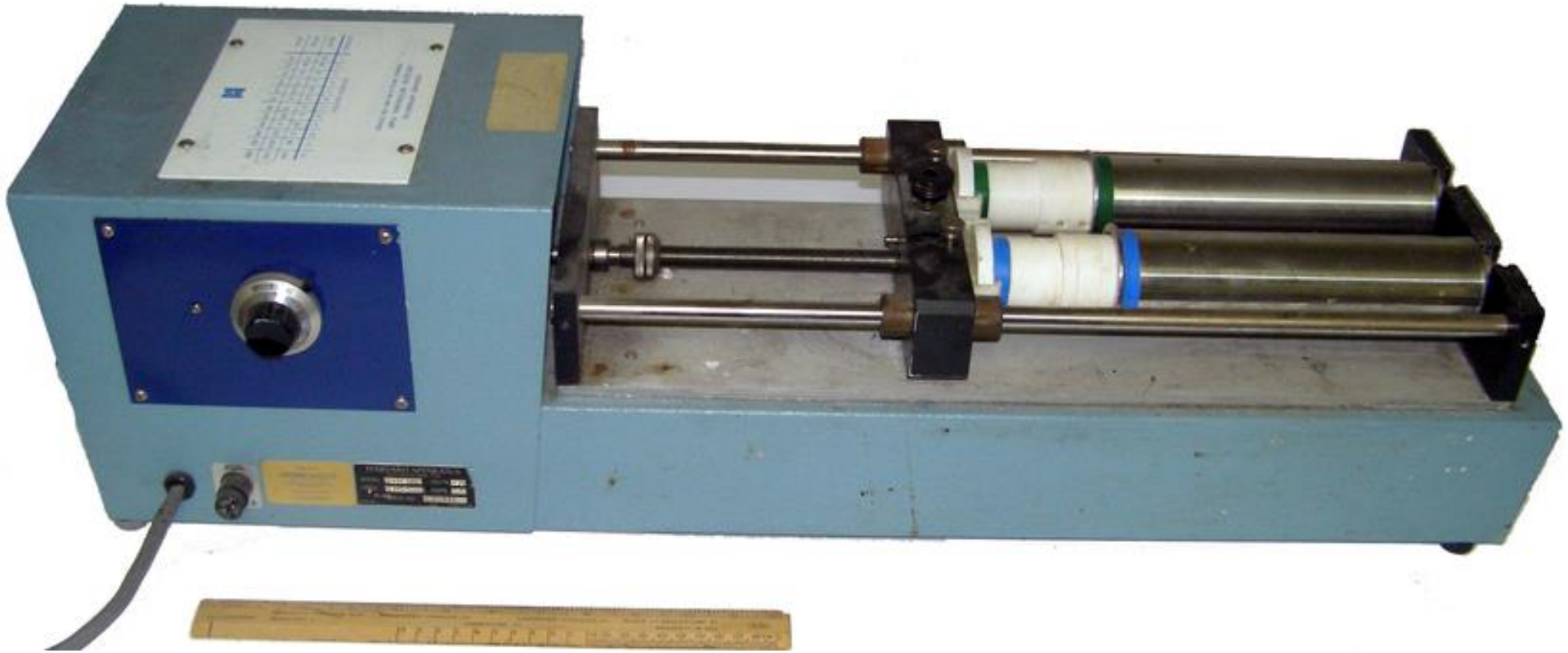

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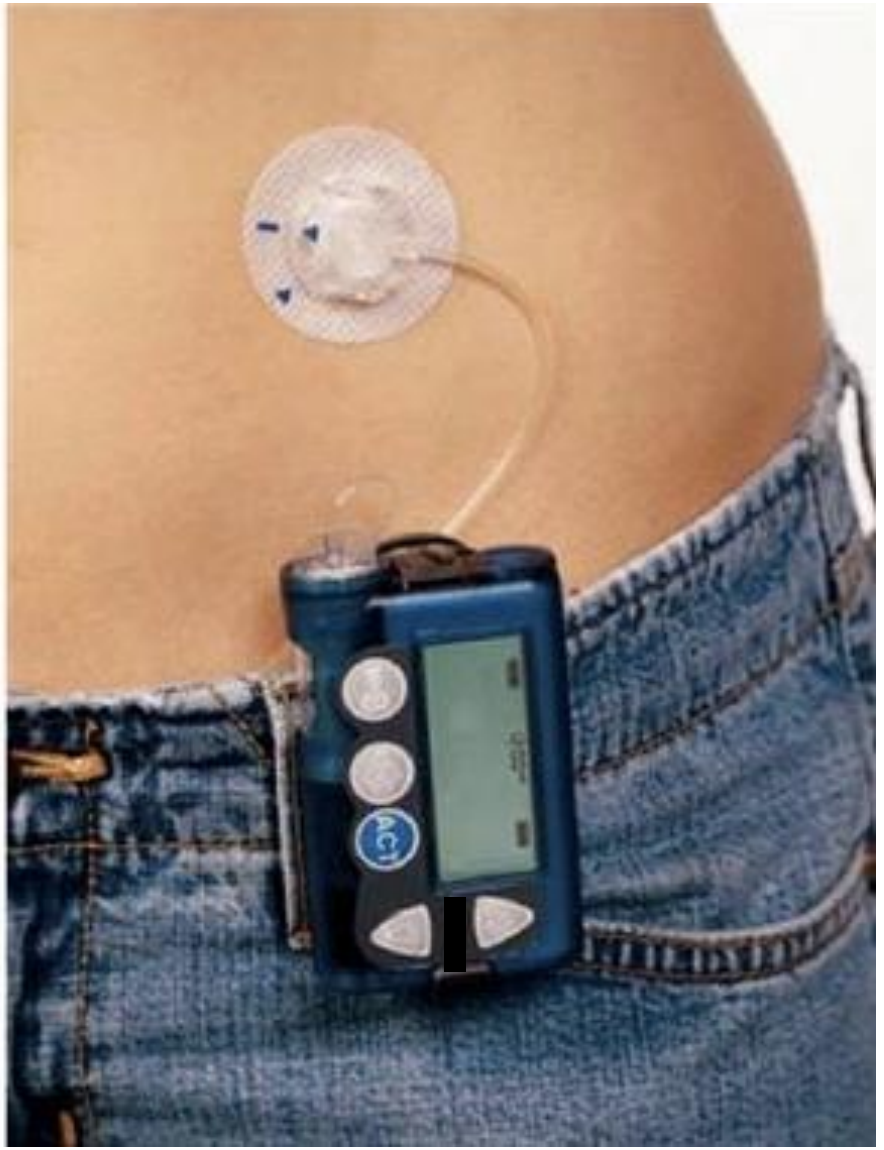

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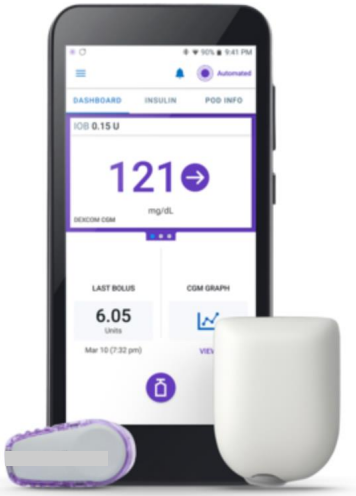
Many options!



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

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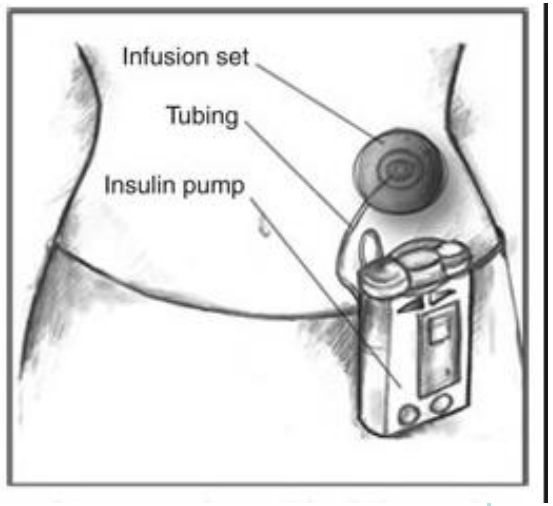
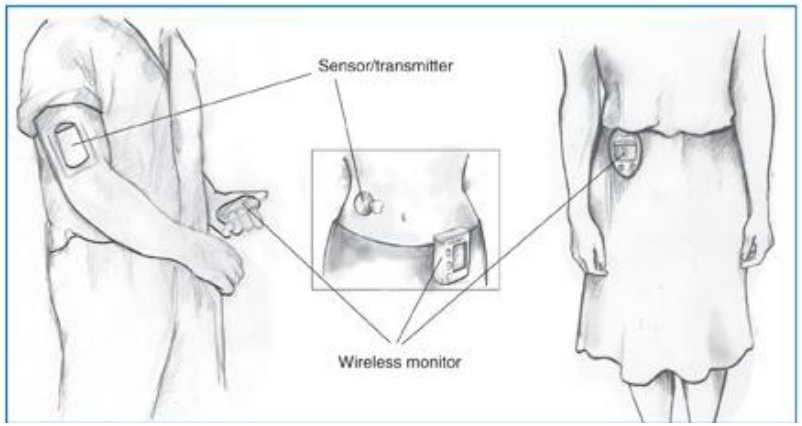
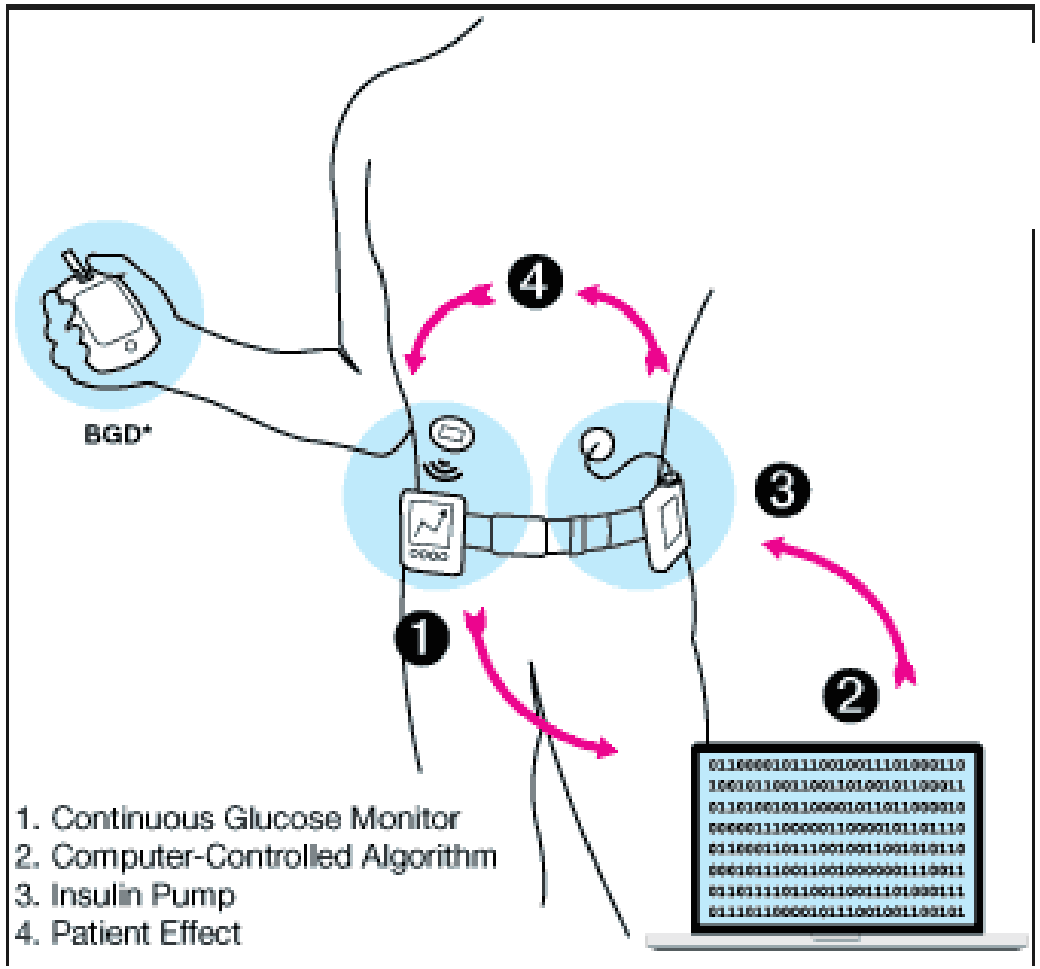
Insulin Pump and CGM

- 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

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Additional Reference CSII with AID Systems

PANTHER® Diabetes Technology. Deciphered.

PANTHERprogram.org

danatech DIABETES TECHNOLOGY @ ADCES

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: 112.5-160 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)?

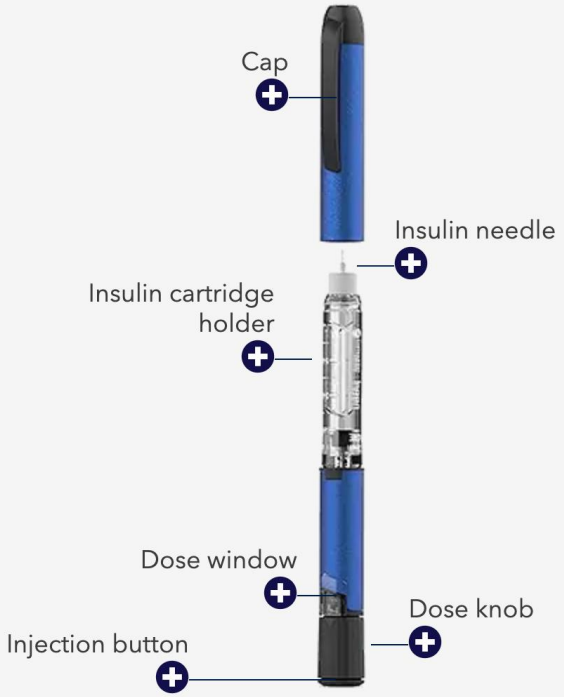
EDUCATE

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?

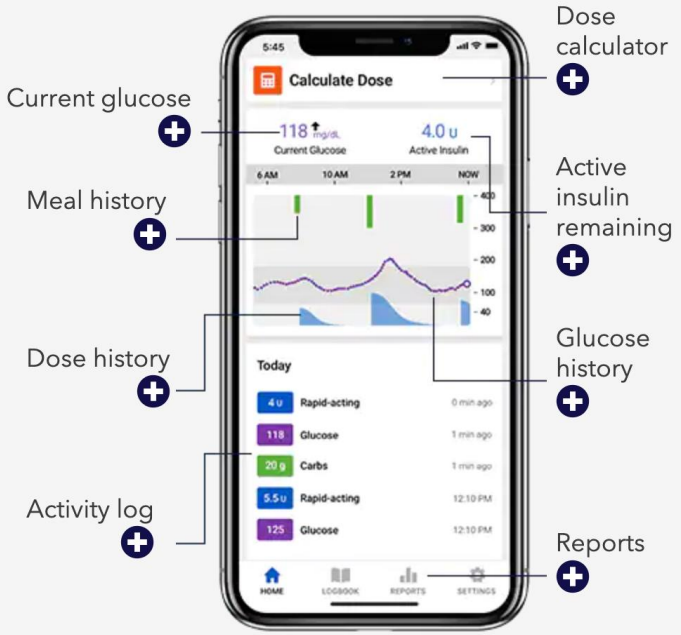
https://www.pantherprogram.org/device-comparison-chart

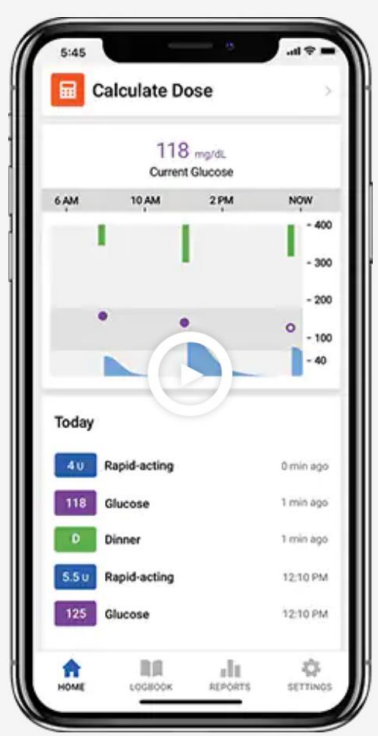
Other Insulin Delivery Devices: Smart Pen In Pen

The pen



The app



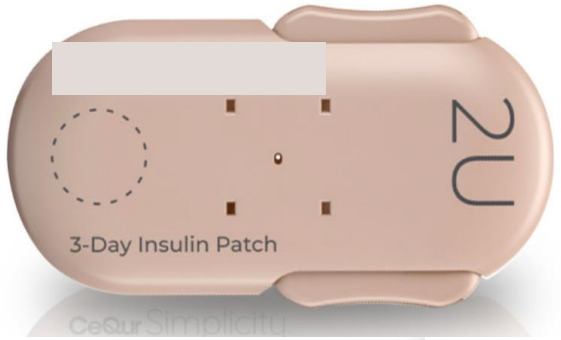


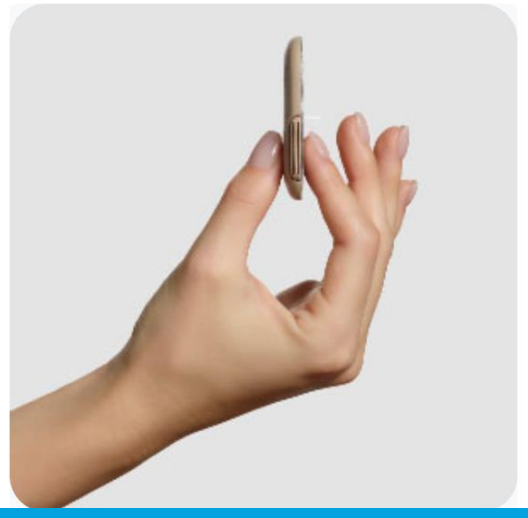
https://www.medtronicdiabetes.com/products/inpen-smart-insulin-pen-system

Other Insulin Delivery Devices: Smart MDI Smart Pen + CGM

https://www.medtronic-diabetes.com/en-gb/SmartMDI

Other Insulin Delivery Devices: Insulin Patch- CeQur

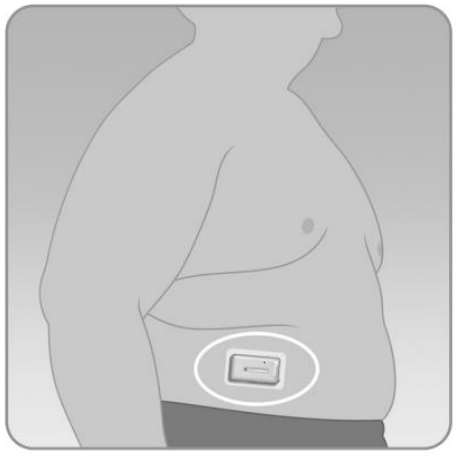


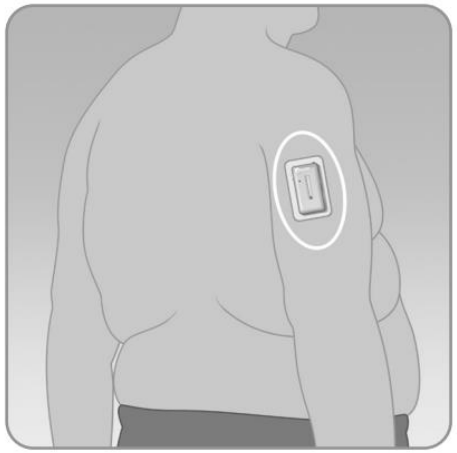


Change every 3 days

https://myceqursimplicity.com/

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

NPDR: non-proliferative diabetic retinopathy
MAU: microalbuminuria

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NPDR: non-proliferative diabetic retinopathy
MAU: microalbuminuria

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**

MDI: multiple daily injections of insulin

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

Advances in Technology…
What's on the Horizon?

Tidepool DIY Loop (January 2023)
Automated Insulin Dosing App

Not currently available

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

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

CGM OTC: Libre Rio (2024)

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

*patients without DM

https://www.betabionics.com/#
https://www.tidepool.org/tidepool-loop
https://investor.tandemdiabetes.com/news-releases/news-release-details/tandem-diabetes-cares-control-iq-automated-insulin-delivery

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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Vigersky RA. The benefits, limitations, and cost-effectiveness of advanced technologies in the management of patients with diabetes mellitus. J Diabetes Sci Technol 2015;9:320–30.