

# Use of Technology in Diabetes Treatment

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## Disclosure

Consultant: Anji; AstraZeneca; Bayer; Boehringer Ingelheim; Corcept; Eli Lilly; Merck; Mineralys; Novo Nordisk; Valo; Vertex; Zealand

Research Grant: Bluedrop; Boehringer Ingelheim; COUR; Eli Lilly; GentiBio; Merck; Roche

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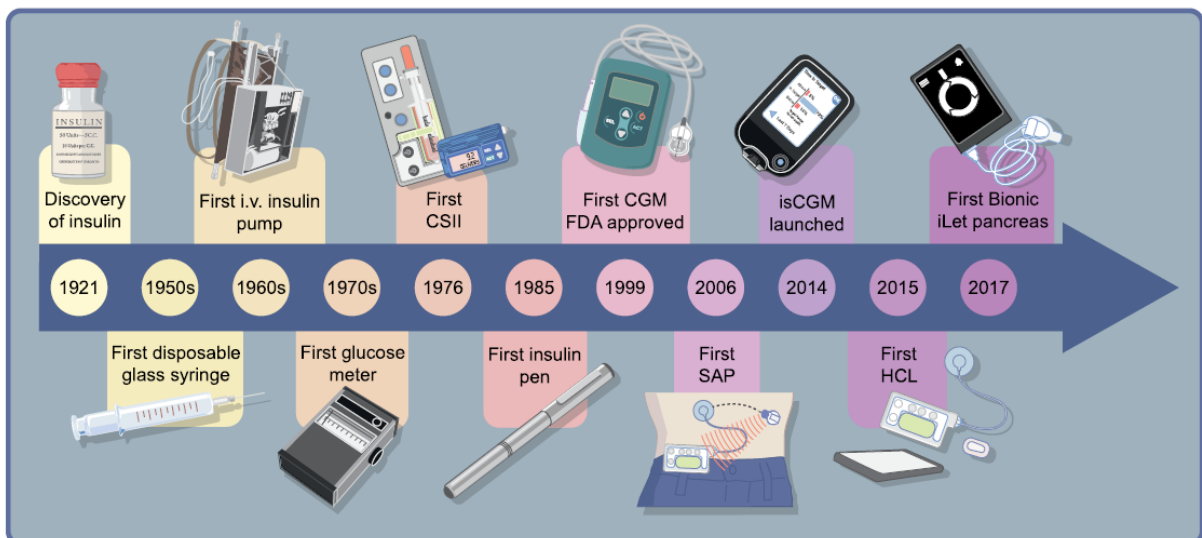
## Technologies in Management of T2DM



- Glucose sensors (CGM)
- Insulin pump basics
- Integrated pumps/sensors
  - *Partially closed-loop systems*
  - *Artificial pancreas*
- Other available technologies
- In-hospital use of diabetes technology

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## Diabetes Technology Timeline



Mallik R, Kar P, Mulder H, Krook A. Diabetologia. 2024 Aug 30. doi: 10.1007/s00125-024-06235-z. Online ahead of print. PMID: 39212678

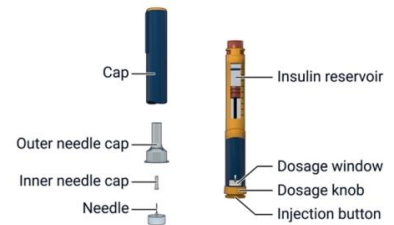
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## Use of Technology in Insulin Therapy



### Many available options:

- Vials
- Pens
  - Disposable (prefilled cartridges)
  - Reusable (Connected Insulin pens/smart pens)
- Insulin pumps/CSII
  - Sensor Augmented pumps
  - Closed loop/hybrid systems
- Disposable insulin patch-like delivery
- Inhaled Insulin



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## Blood Glucose Monitoring



Patients with type 2 diabetes on intensive insulin therapy will need frequent glucose monitoring

- To ensure patient safety
- To guide regimen modification
- Often needed before meals, before driving, bed time, post meals, after correcting hypoglycemia, before exercise...



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## Continuous Glucose Monitoring (CGM)

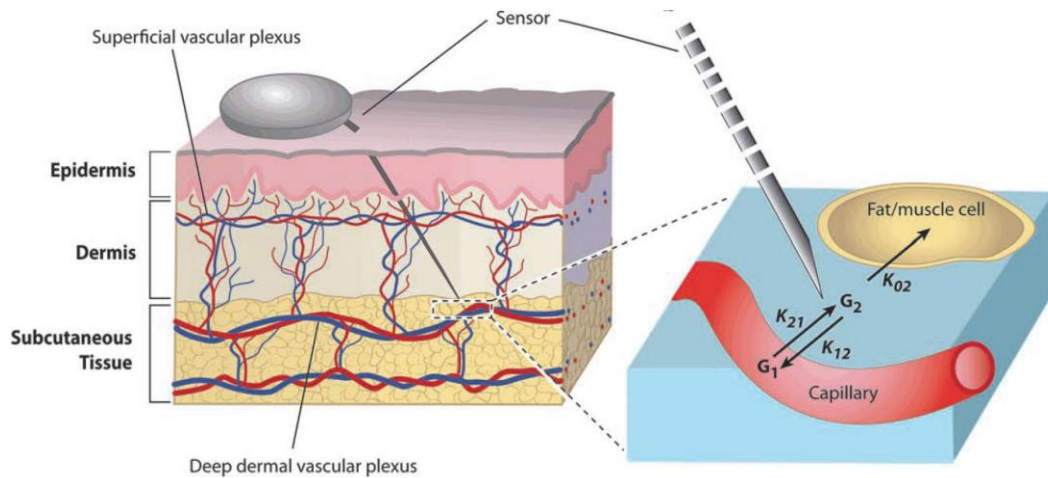


Figure: Cengiz and Tamborlane. Diabetes Technol Ther. 2009. Jun;11 (Suppl 1)

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## Why Is CGM Important?



**HbA1c is not the whole story!**

Ajjan R, Slattery D, Wright E. Continuous Glucose Monitoring: A Brief Review for Primary Care Practitioners. Adv Ther. 2019 Mar;36(3):579-596. doi: 10.1007/s12325-019-0870-x. Epub 2019 Jan 18. PMID: 30659511; PMCID: PMC6824352.

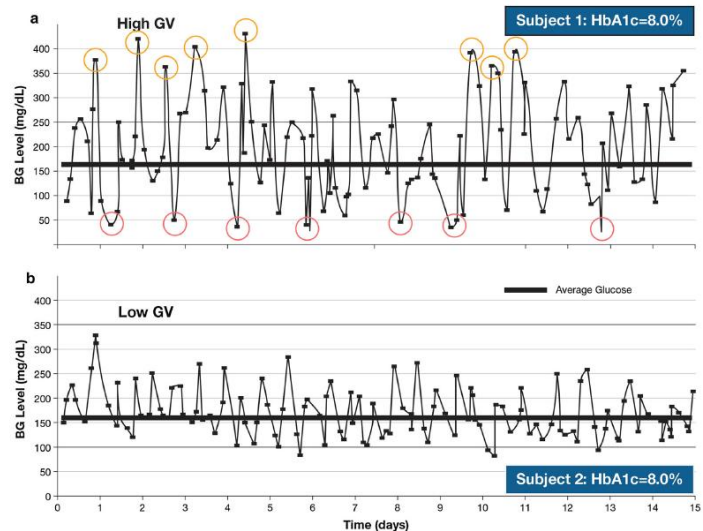


Fig. 1 Differences in glycemic variability over 15 days for two patients with similar HbA1c levels. BG blood glucose, GV glycemic variability, HbA1c glycated hemoglobin A<sub>1c</sub>

Reproduced from Kovatchev and Cobelli [16] © 2016 by the American Diabetes Association

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## 7. Diabetes Technology

## General Device Principles

**7.1** Diabetes devices should be offered to people with diabetes. **A**

**7.2** The type(s) and selection of devices should be individualized based on a person's specific needs, circumstances, preferences, and skill level. In the setting of an individual whose diabetes is partially or wholly managed by someone else (e.g., a young child or a person with cognitive impairment or dexterity, psychosocial issues, and/or physical limitations), the caregiver's skills and preferences are integral to the decision-making process. **E**

**7.3a** When prescribing a continuous glucose monitoring (CGM) device, ensure that people with diabetes and caregivers are offered initial and ongoing training and education as indicated by individual circumstances. Education should include utilization of data, including uploading or sharing data to monitor and adjust therapy. **C**

**7.3b** When prescribing an automated insulin delivery (AID) system, people with diabetes and their caregivers must receive education on how to use and troubleshoot the system. This education should occur at regular intervals as needed. Education should include utilization of the integrated system and its data, including uploading or sharing data to monitor and adjust therapy. **C**

Standards of Medical Care in Diabetes—2026. American Diabetes Association. Diabetes Care 2026 Jan; Volume 49, Issue Supplement 1



## 7. Diabetes Technology

## General Device Principles (Continued)

**7.4** Health care professionals working with people with diabetes should be aware of available technologies and seek additional support when needed. **E**

**7.5** People with diabetes using CGM, continuous subcutaneous insulin infusion (CSII), and/or AID for diabetes management should have continued access to devices across third-party payors, regardless of age or A1C levels. **E**

**7.6** Children and adolescents should be supported at school in the use of diabetes technology, such as CGM systems, CSII, connected insulin pens, and AID systems. **E**

**7.7** For adults with diabetes using diabetes technology, reasonable accommodations in educational and work settings should include having sufficient time to manage their devices and respond to high and low glucose levels. **E**

Standards of Medical Care in Diabetes—2026. American Diabetes Association. Diabetes Care 2026 Jan; Volume 49, Issue Supplement 1



## 7. Diabetes Technology

## General Device Principles (Continued)

**7.8** Consider early initiation, including at diagnosis, of CGM, CSII, and AID depending on a person's or caregiver's needs and preferences. **C**

**7.8a** There should be no requirement of C-peptide level, **B** the presence of islet autoantibodies, **B** or duration of insulin treatment **C** before initiation of CSII or AID.

**7.9** Standardized reports for all CGM, CSII, AID, and connected insulin devices with a minimum of a single-page report, such as the ambulatory glucose profile and weekly summary, should be available and utilized. Options for daily and weekly reports and raw data should be available. **E**

Standards of Medical Care in Diabetes—2026. American Diabetes Association. Diabetes Care 2026 Jan; Volume 49, Issue Supplement 1



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## Personal CGM Devices Prescribed

	G6	G7	Libre 2	Libre 3	Guardian Connect and Guardian 4	Eversense
Insulin pump compatibility	T: Slim X2, iLet, Mobi, Omnipod 5	T: Slim X2, iLet, Mobi, Omnipod 5	T: Slim X2 (2+)	iLet, Twist (3+)	Minimed 780G	None
Maximum wear time <sup>a</sup>	10 days	10.5 days	14 days (15 days with Libre2+ and 3+)		7 days	1 year
Warm-up time	2 hours	30 min	1 hour		Up to 2 hours	24 hours
Calibrations required	0	0	0		At least 2/day	2/day for 21 days, then 1/day
Water depth	8 feet, 24 hours	8 feet, 24 hours	3 feet, 30 min		8 feet, 30 min	3.28 feet, 30 min
Data Platform	Dexcom Clarity		LibreView		Carelink	Eversense Data Management System

Product User Guides

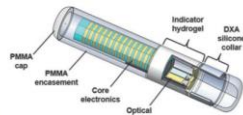
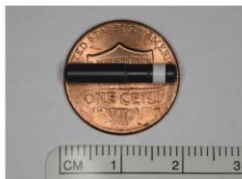
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## Eversense CGM



### • Implantable sensor

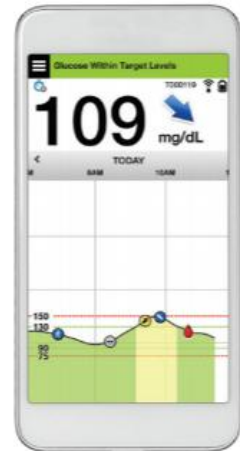
- Inserted subcutaneously upper arm
- Transmitter worn over sensor
- Mobile app displays data
- Up to 12-month sensor life (USA)
- Phone and on-body alerts



Sensor



Smart Transmitter



Eversense App

<https://www.eversensed diabetes.com/healthcare-professionals/>

Kropff, J., Choudhary, P., Neupane, S., Barnard, K., Bain, S. C., Kapitza, C., ... & DeVries, J. H. (2017). Accuracy and longevity of an implantable continuous glucose sensor in the PRECISE study: a 180-day, prospective, multicenter, pivotal trial. *Diabetes Care*, 40(1), 63-68. (PRECISE I).

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## Personal CGM Devices Prescribed, Cont

	G6	G7	Libre 2	Libre 3	Guardian Connect	Eversense
FDA approved sites	Abdomen (ages 2+) Upper buttocks (ages 2-17)	Upper arm (ages 7+) Upper buttocks (ages 2-6)	Upper arm		Upper arm, abdomen Upper buttocks (ages 2-13)	Upper arm
Approved in pregnancy	No	Yes	Yes		No	No
Transmitter	3 months	Disposable	Disposable		Charge weekly	Charge daily
FDA-approved ages (years)	≥ 2	≥ 2	≥ 4 (≥2 with Libre2+ and 3+)		≥ 2, Guardian 4 ≥14, Guardian Connect	≥ 18
Drug interactions	Hydroxyurea	Hydroxyurea	Vitamin C (less with Libre 2+ and 3+)		Acetaminophen, hydroxyurea	Tetracycline antibiotics, mannitol

Product User Guides

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## Personal CGM Comparison OTC

	Lingo, Lingo Rio	Stelo
Type	rtCGM	rtCGM
Maximum wear time	14 days	15 days
Warm-up time	1 hour	<30 min
Fingerstick calibrations required	No	No
Sharing data	NA	Dexcom Clarity
FDA approved sites	Back of upper arm	
Transmitter	Disposable	Disposable
FDA cleared use	Adults 18+ with prediabetes or type 2 diabetes who do not use insulin.	Adults 18+ with prediabetes or type 2 diabetes who do not use insulin.
Water depth	3 feet, 30 min	8 feet, 24 hours
Drug interactions	Vitamin C	Hydroxyurea
Cost	\$49 for 1 sensor, \$89 for 2 sensors	\$99 for two sensors (a 30-day supply) with a 10% discount for monthly subscription.

Product User Guides

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## Factors Influencing CGM System Preference

- Cost
- Duration of wear
- Location for use
- Size
- Ease of use
- Compatibility with other devices/mobile apps
- Remote monitoring

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## Good Candidates for Personal CGM



Patients with the following diagnoses are considered good candidates for CGM.

### GOOD CANDIDATES FOR CGM

Patients with the following diagnoses are considered good candidates for CGM.

Diagnosis	Type 1 diabetes	Type 2 diabetes
Diabetes mellitus with hyperglycemia	E10.65	E11.65
Diabetes mellitus with hypoglycemia without coma	E10.649	E11.649
Diabetes mellitus with hyperglycemia during pregnancy	O24.011–O24.013	O24.111–O24.113
Labile blood glucose	R73.09	

<https://www.aafp.org/pubs/fpm/issues/2021/0300/p7.html>

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## CMS CGM Coverage

Meet at least one of the following criteria:



Treated with **insulin**

OR



Documented **history of problematic hypoglycemia**

ICD-10 code<sup>2</sup>: E16.A2  
hypoglycemia level 2

- **Recurrent level-2 hypoglycemic events** (glucose <54 mg/dL)

- Despite 2 or more attempts to adjust medication or modify treatment plan

OR

ICD-10 code<sup>2</sup>: E16.A3  
hypoglycemia level 3

- A history of **one level-3 hypoglycemic event** (glucose <54 g/dL)

- Requiring third-party assistance for treatment of hypoglycemia

As long as the beneficiary uses any insulin, the beneficiary is eligible for CGM coverage

CGM, continuous glucose monitoring; CMS, Centers for Medicare & Medicaid Services.  
Centers for Medicare & Medicaid Services. Accessed March 2, 2023. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822>. 2 ICD10Data.com. October 1, 2024. Accessed January 7, 2025.  
[https://www.icd10data.com/ICD10CM/Codes/Changes/New\\_Codes/1?year=2025](https://www.icd10data.com/ICD10CM/Codes/Changes/New_Codes/1?year=2025).

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# Interpret Data, Evaluate the Plan and Bill

## 2024 Continuous Glucose Monitoring CPT Coding Reference<sup>\*,†,‡,§,¶</sup>

CPT 95251 CGM Interpretation	Medicare physician office fee schedule*	Private payer†	Relative value unit (RVU) non-facility‡
Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a <b>minimum of 72 hours</b> ; analysis, interpretation and report.	\$34.29	\$98.00	1.03

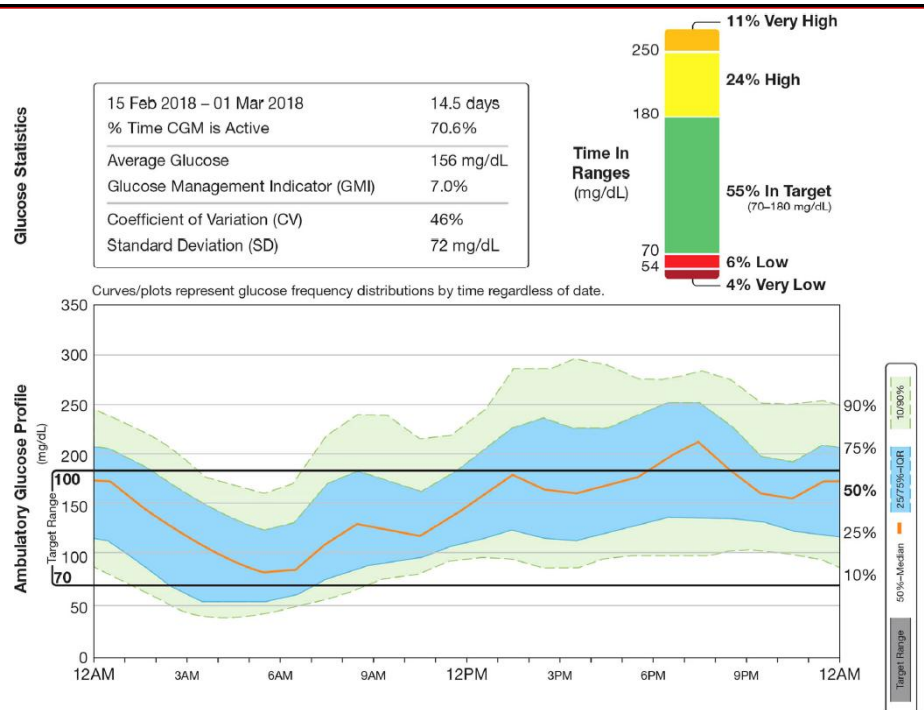
Do not bill 95251 more than 1 time per month<sup>||</sup>

\* The reimbursement information provided is intended to assist you with billing for your services related to continuous glucose monitoring (CGM). It is intended for informational purposes only and is not a guarantee of coverage and payment.  
† Physician fee schedule numbers represent estimated 2024 physician payment amounts using the total non-facility RVUs in the CY 2024 Physician Fee Schedule rule Addendum B and the conversion factor. These numbers are not adjusted for locality. Effective for services on or after March 9, 2024. ‡ PMIC Medical Fees Directory. Numbers provided are the 50th percentile of the Usual and Customary (UCR) charges. Note that these are charges and not actual reimbursed amounts.  
§ Relative Value Unit (RVU) Non-Facility reference the numbers found in the 2024 Physician Fee Schedule Relative Value Files under Total Non-Facility RVUs. ¶ CPT is a registered trademark of the American Medical Association. || Frequency may vary by individual payer. Check with individual payer for specifics.  
CPT, current procedural terminology; RVU, relative value unit.  
¶ CPT 2024 Professional Edition / American Medical Association. Fourth edition, revised 2023. American Medical Association; 2023.

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## Example CGM Report

Ajjan R, Slattery D, Wright E.  
Continuous Glucose Monitoring: A  
Brief Review for Primary Care  
Practitioners. Adv Ther. 2019  
Mar;36(3):579-596. doi:  
10.1007/s12325-019-0870-x. Epub  
2019 Jan 18. PMID: 30659511;  
PMCID: PMC6824352.



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## CGM Time-in-Range (TIR) Targets

T1D &  
T2D

**TAR <5%** >250 mg/dl  
>13.9 mmol/l

**TAR <25%** >180 mg/dl  
>10.0 mmol/l

**TIR >70%** 70–180 mg/dl  
3.9–10.0 mmol/l

**TBR <4%** <70 mg/dl  
<3.9 mmol/l

**TBR <1%** <54 mg/dl  
<3.0 mmol/l

### Why 70% TIR Target?

<sup>1</sup>Beck RW, Bergenstal RM, Cheng P, Kollman C, Carlson A, Johnson M, Rodbard D, Relationship Between TIR and Hyperglycemic Metrics and HbA1c *J Diabetes Sci Technol* 2019;13:614-626

1.

#### TIR–A1C correlation<sup>1</sup>

TIR 70%  $\approx$  A1C 7%

TIR 50%  $\approx$  A1C 8%

10%  $\Delta$ TIR  $\approx$  0.5%  $\Delta$ A1C

2. 70% TIR is achievable in practice: (T1D with HCL therapy & T2D following algorithm)

TIR Targets vary for Special Populations – for instance:

Pregnancy & DM-- TIR >70% but for 63-140 mg/dL target zone

Older/High Risk-- TIR >50% TIR 70-180 ; <1% <70 mg/dL

Battelino T, Danne T, Bergenstal RM, et al. International TIR Consensus *Diabetes Care* 2019;42:1593–1603

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## Derived TIR and Microvascular Complications

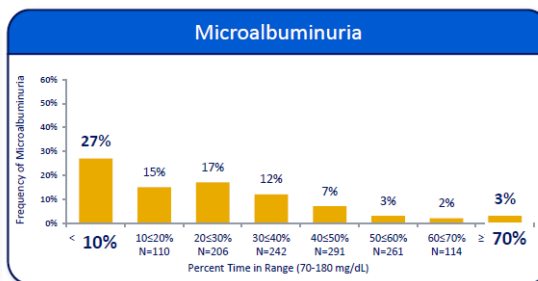
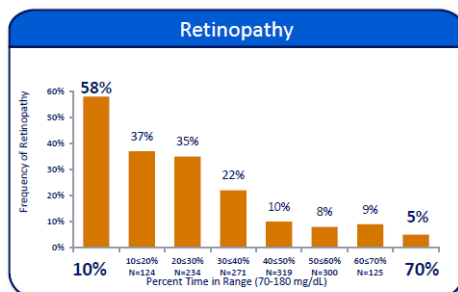
### Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials

<https://doi.org/10.2337/dc18-1444>

Roy W. Beck,<sup>1</sup> Richard M. Bergenstal,<sup>2</sup>  
Tonya D. Riddleworth,<sup>1</sup> Craig Kollman,<sup>1</sup>  
Zhaoan Li,<sup>1</sup> Adam S. Brown,<sup>1</sup> and  
Kelly L. Close<sup>4</sup>

#### Relationship between TIR (70–180) and Eye & Kidney Complications

(TIR: derived from 7-point SMBG profiles on 1,440 patients in DCCT performed 4 times/yr for up to 10 yrs)



For each 10% less TIR, retinopathy progression increased by 64% (95% CI: 51–78), and microalbuminuria outcome by 40% (95% CI: 25–56);  $p < 0.001$  for each

Beck RW, Bergenstal RM, Riddleworth TD et al. *Diabetes Care*. 2019;42:400–5.

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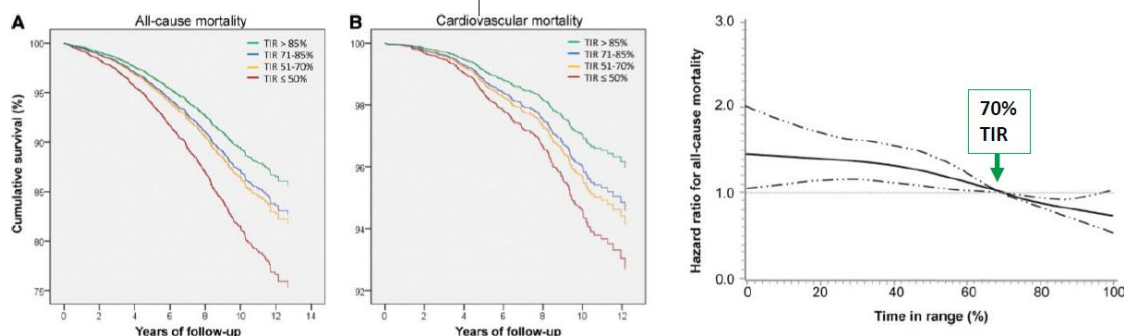
## TIR and Macrovascular Complications



Time in Range in Relation to All-Cause and Cardiovascular Mortality in Patients With Type 2 Diabetes: A Prospective Cohort Study *Diabetes Care* 2021 Feb; 44(2): 549-555

Jingyi Lu,<sup>1</sup> Chunfang Wang,<sup>2</sup> Yun Shen,<sup>1</sup> Lei Chen,<sup>2</sup> Lei Zhang,<sup>2</sup> Jinghao Cai,<sup>2</sup> Wei Lu,<sup>1</sup> Wei Zhu,<sup>3</sup> Gang Hu,<sup>2</sup> Jien Xia,<sup>4</sup> and Jian Zhou<sup>1</sup>

- 6,225 T2D – CGM (72 hrs)
- Followed 10 years (2005-2015)
- Association baseline TIR & Mortality
  - All cause & CV mortality



**Figure 1**—Multivariate-adjusted cumulative survival curves of all-cause (A) and cardiovascular (B) mortality by different levels of TIR. Adjusted for age, sex, BMI, diabetes duration, systolic blood pressure, triglyceride, HDL cholesterol, LDL cholesterol, smoking status, history of cancer and CVDs, and using antihypertensive drugs, aspirin, and statins.

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## CGM Patient Example



57-year-old man with type 2 diabetes for 10 years. Initially treated with metformin but regimen steadily intensified over time

- **Med Hx:** HTN, HL, CAD, OSA
- **Surg Hx:** Chole, Appendectomy
- **Fam Hx:** Diabetes, stroke, CAD
- **Soc Hx:** No smoking, no alcohol, banker
- **Diet:** 2 meals, 1 snack at times, avoids simple sugars
- **Exercise:** Walks the dog daily

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## CGM Patient Example



- **Current medications:**
  - Empagliflozin 25 mg daily
  - Metformin 1000 mg BID
  - Glargine 20 units QHS
  - Lisinopril, ASA, Carvedilol
- **Physical examination:**
  - BP 117/80, HR 70, Wt. 70 Kg, BMI 29
- **Labs:** A1c 9%, Cr 1.0, eGFR 60

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## CGM Patient Example



Average Glucose

# 208

 mg/dL
Standard Deviation  
**41** mg/dLGMI  
**N/A**

Time in Range

■ 16% Very High  
■ 55% High  
■ **29% In Range**  
■ 0% Low  
■ 0% Very Low

Target Range:  
70-180 mg/dL

Sensor Usage

Days with CGM data  
**53%**  
8/15Avg. calibrations per day  
**0.0**

Glucose Statistics

Avg Glucose  
mg/dL

**208**

Glucose Exposure

Very Low	Low	In Target Range	High	Very High
< 54 mg/dL	< 70 mg/dL	70 - 180 mg/dL	> 180 mg/dL	> 250 mg/dL
<b>0.0%</b>	<b>0.0%</b>	<b>28.8%</b>	<b>71.2%</b>	<b>16.1%</b>
Glucose Ranges				

Coefficient of  
Variation

**19.6%**

SD  
mg/dL

**41**

Glucose Variability

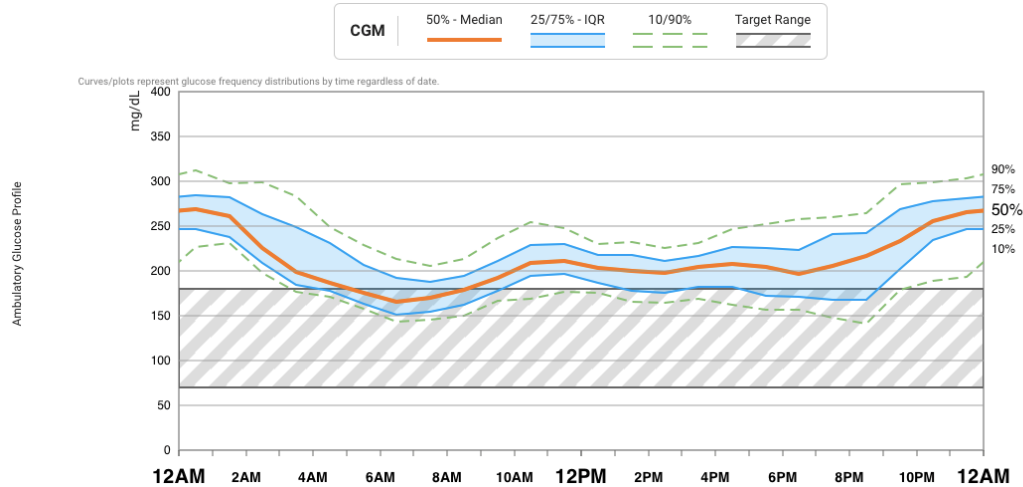
% Time CGM  
Active

**87.3%**

Data Sufficiency

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## CGM Patient Example



*What should happen now?*

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## CGM Patient Example – After Regimen Adjustment



Average Glucose

# 159

mg/dL

Standard Deviation

## 31

mg/dL

GMI

## N/A

Time in Range

<1% Very High  
25% High  
**74% In Range**  
0% Low  
0% Very Low

**Target Range:**  
70-180 mg/dL

Sensor Usage

Days with CGM data

## 93%

13/14

Avg. calibrations per day

## 0.0

Glucose Statistics

Avg Glucose  
mg/dL

## 159

Glucose Exposure

Very Low	Low	In Target Range	High	Very High
< 54 mg/dL	< 70 mg/dL	70 - 180 mg/dL	> 180 mg/dL	> 250 mg/dL
0.0%	0.0%	73.9%	26.1%	0.2%
Glucose Ranges				

Coefficient of  
Variation

## 19.8%

SD  
mg/dL

## 31

Glucose Variability

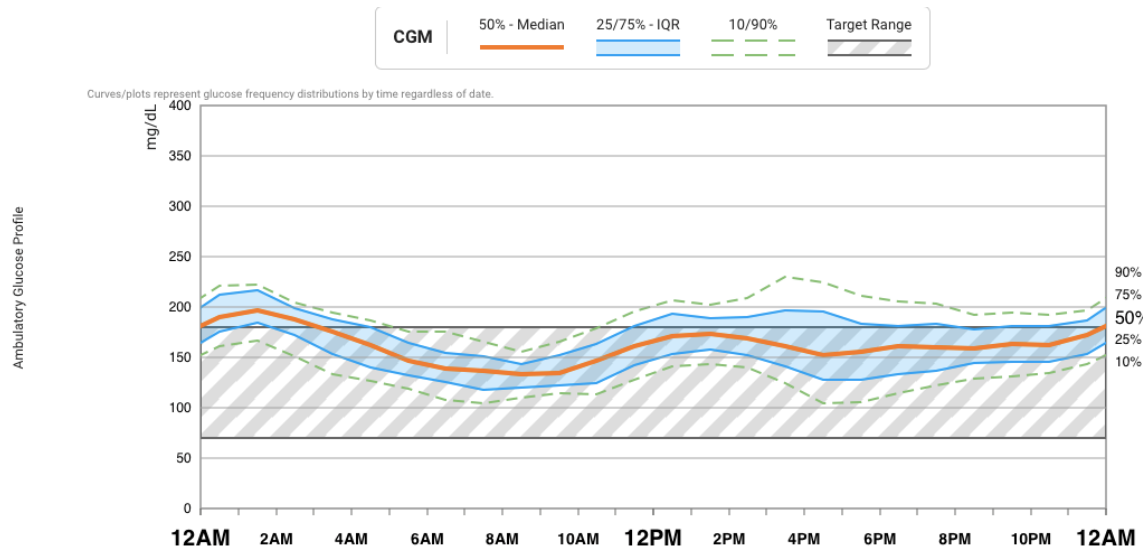
% Time CGM  
Active

## 81.3%

Data Sufficiency

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## CGM Patient Example – After Regimen Adjustment



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## Cost Comparison

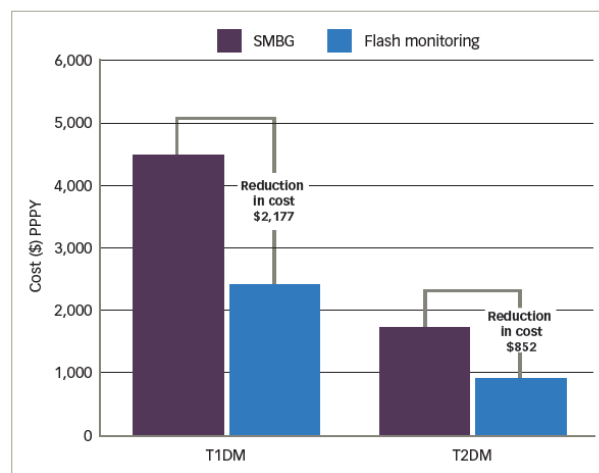


### Patients on Intensive Insulin Therapy

- Acquisition cost of Flash CGM is lower than SMBG in patients checking BG  $\geq 3$  times per day
- Costs associated with severe hypoglycemia expected to be lower with Flash CGM
  - More significant in T1DM than T2DM

Lizheng Shi, Richard Hellmund. Cost Comparison of Flash Continuous Glucose Monitoring with Self-monitoring of Blood Glucose in Adults with Type 1 or Type 2 Diabetes Using Intensive Insulin—From a US Private Payer Perspective. DOI: <https://doi.org/10.17925/USE.2020.16.1.24>

Figure 2: Reduction in estimated costs of severe hypoglycemic events for patients with type 1 and type 2 diabetes



PPPY = per patient per year; SMBG = self-monitoring of blood glucose; T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus.

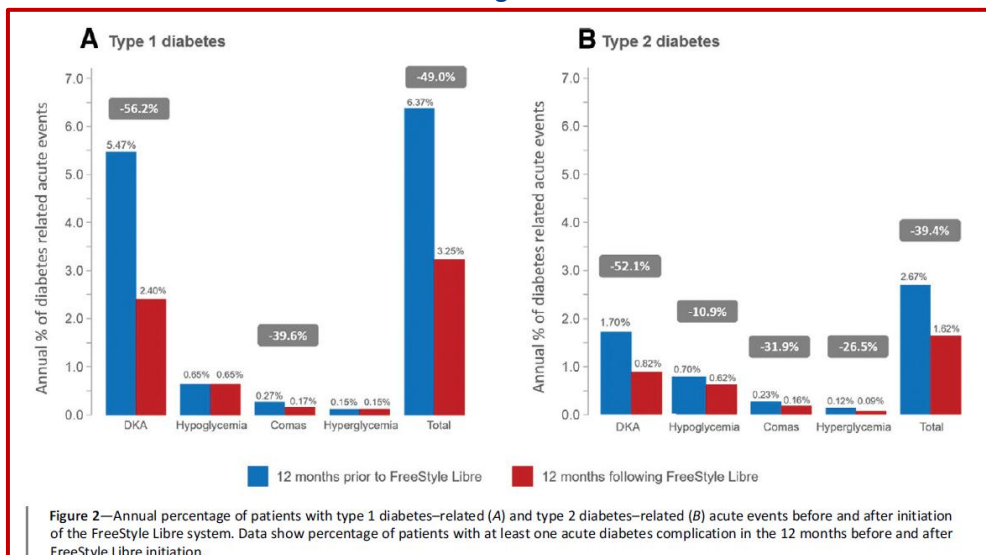
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## Real-World Outcomes with Flash CGM



74,011 patients in France with T1DM or T2DM starting Flash CGM



Roussel R et al. Important Drop Rate of Acute Diabetes Complications in People With Type 1 or Type 2 Diabetes After Initiation of Flash Glucose Monitoring in France: The RELIEF Study. Diabetes Care. 2021 Apr 20;dc201690. doi: 10.2337/dc20-1690. Epub ahead of print. PMID: 33879536.

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## US Real-World Outcomes with Flash CGM

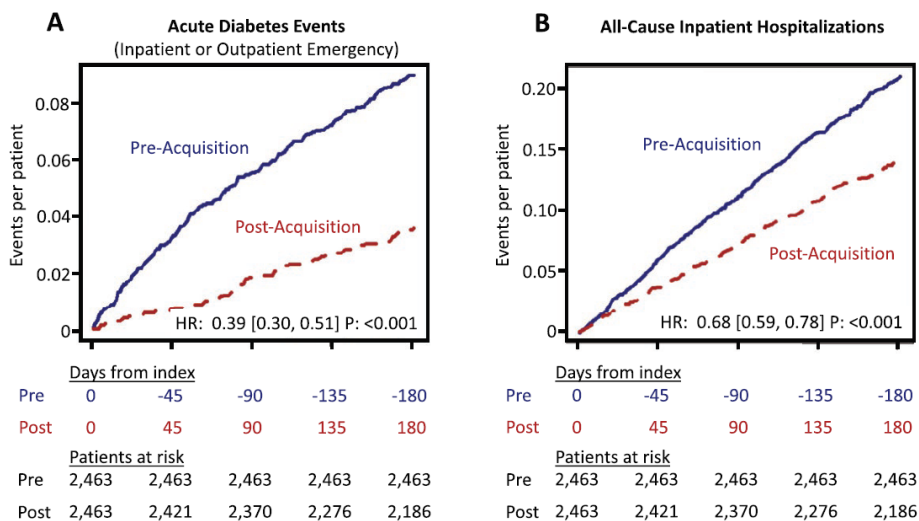


- IBM Watson Health MarketScan Commercial Claims and Medicare Supplemental databases
- 2463 adults with T2DM who were on short- or rapid-acting insulin therapy, who had started a Flash CGM system
- Outcomes were changes in acute diabetes-related events (ADE) and all-cause inpatient hospitalizations (ACH), 6 months pre and post acquiring CGM
- ADE = hypoglycemia, hypoglycemic coma, clinical hyperglycemia, diabetic ketoacidosis, and hyperosmolarity.

Bergental RM et al. Flash CGM Is Associated With Reduced Diabetes Events and Hospitalizations in Insulin-Treated Type 2 Diabetes. J Endocr Soc. 2021 Feb 2;5(4):bvab013. doi: 10.1210/endo/bvab013. PMID: 33644623; PMCID: PMC7901259.

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# US Real-World Outcomes with Flash CGM



Bergental RM et al. Flash CGM Is Associated With Reduced Diabetes Events and Hospitalizations in Insulin-Treated Type 2 Diabetes. J Endocr Soc. 2021 Feb 2;5(4):bvab013. doi: 10.1210/endo/bvab013. PMID: 33644623; PMCID: PMC7901259.

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## Insulin Pump Basics



\*Some pumps are tubeless

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## Advantages to Insulin Pump Therapy



- More closely approximates physiologic insulin secretion
- Can administer very small doses of insulin accurately
- Flexibility in insulin dosing to accommodate lifestyle needs (i.e. reduced basal rates for physical activity)
- Improved quality of life for many patients
- Improvement in glycemic control
- Reduction in rates of severe hypoglycemia and DKA\*

\*Some studies have shown increased rates DKA

Eitler, K. et al. Continuous subcutaneous insulin infusion versus multiple daily insulin injections in patients with diabetes mellitus: systematic review and meta-analysis. *Diabetologia* 51, 941–951 (2008). PubMed Article CAS Google Scholar

Fatourehchi, M. M. et al. Clinical review: hypoglycemia with intensive insulin therapy: a systematic review and meta-analyses of randomized trials of continuous subcutaneous insulin infusion versus multiple daily injections. *J. Clin. Endocrinol. Metab.* 94, 729–740 (2009). PubMed Article CAS Google Scholar

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## Rationale and Indications for CSII in T2DM



- Insulin pump therapy **can be** offered for diabetes management to youth and adults on multiple daily injections with type 2 diabetes who are capable of using the device safely (either by themselves or with a caregiver).
- The choice of device should be made based on patient circumstances, desires, and needs.

*Diabetes Care* 2017;40: 715-722

*Diabetes Technology & Therapeutics* 2016; 18:22-28

*Diabetes Obes Metab.* 2020; 22: 434-441

*Diabetes Care.* 2023 Jan 1;46(Suppl 1):S49-S67. doi: 10.2337/dc23-S004

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## CGM Integration



t:slim Basal IQ



InPen smart pen



Medtronic 770G



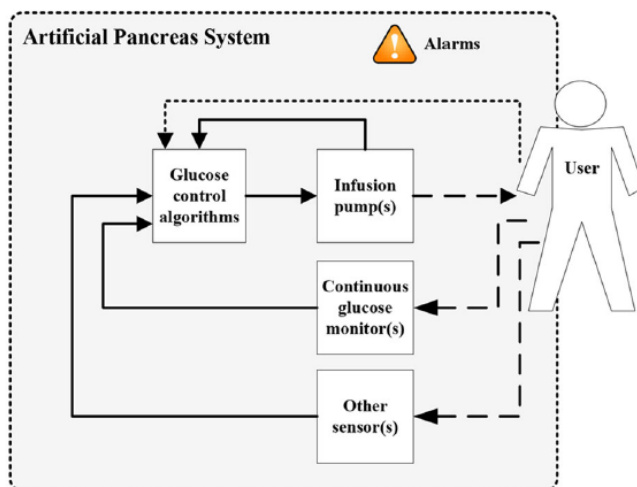
t:slim Control IQ



Medtronic 670G

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## Components of Artificial Pancreas System



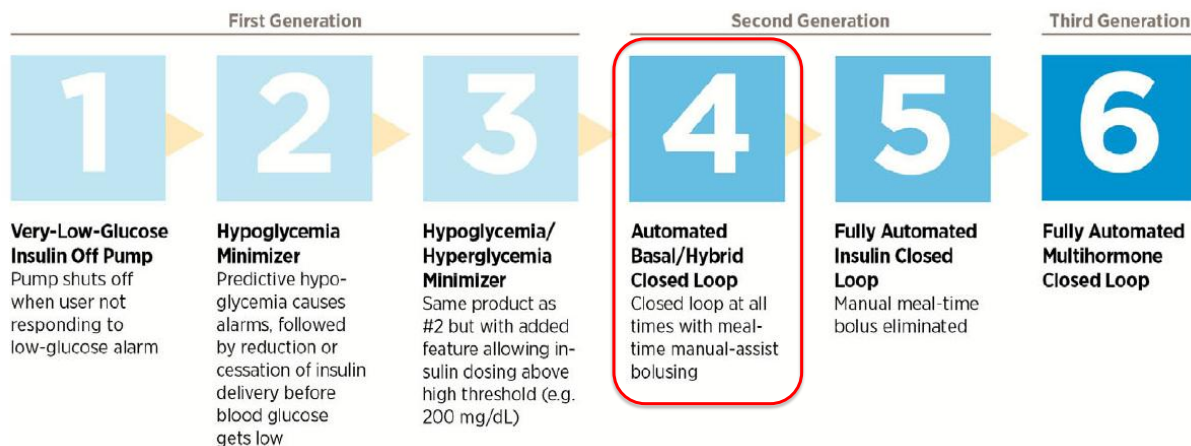
### Three Main Components

- Continuous glucose monitor (CGM)
- Glucose control algorithm(s)
- Insulin infusion pump

Blauw et al, Annals of Biomedical Engineering, Vol. 44, No. 11, November 2016 pp. 3158–3172

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## JDRF Roadmap to the Artificial Pancreas



The JDRF six developmental stages of artificial pancreas device systems

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## Example Available Hybrid Closed-Loop Device



### Tandem Control IQ Insulin Pump

- Approved for use with Dexcom G6 CGM
- Hybrid Closed Loop system (Control IQ) automatically adjusts insulin levels based on CGM readings
- Can deliver correction boluses



<https://www.tandemdiabetes.com/products/t-slim-x2-insulin-pump>

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## Artificial Pancreas



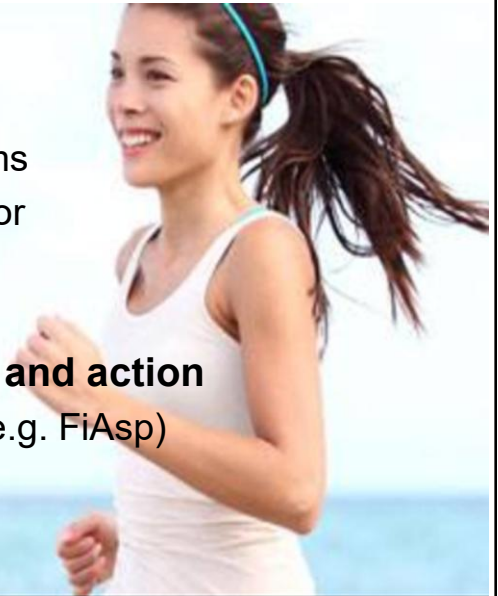
- **Challenges:**

- **Food intake and exercise**

- Bihormonal (insulin + glucagon) systems
    - Use of accelerometer, heart rate monitor
    - Adjunctive therapies
      - pramlintide, GLP-1RA, DPP4i

- **Time delay between insulin delivery and action**

- Use of more rapidly absorbed insulin (e.g. FiAsp)
    - Intraperitoneal delivery of insulin



Blauw et al, Annals of Biomedical Engineering, Vol. 44, No. 11, November 2016 pp. 3158–3172

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## Bihormonal Artificial Pancreas

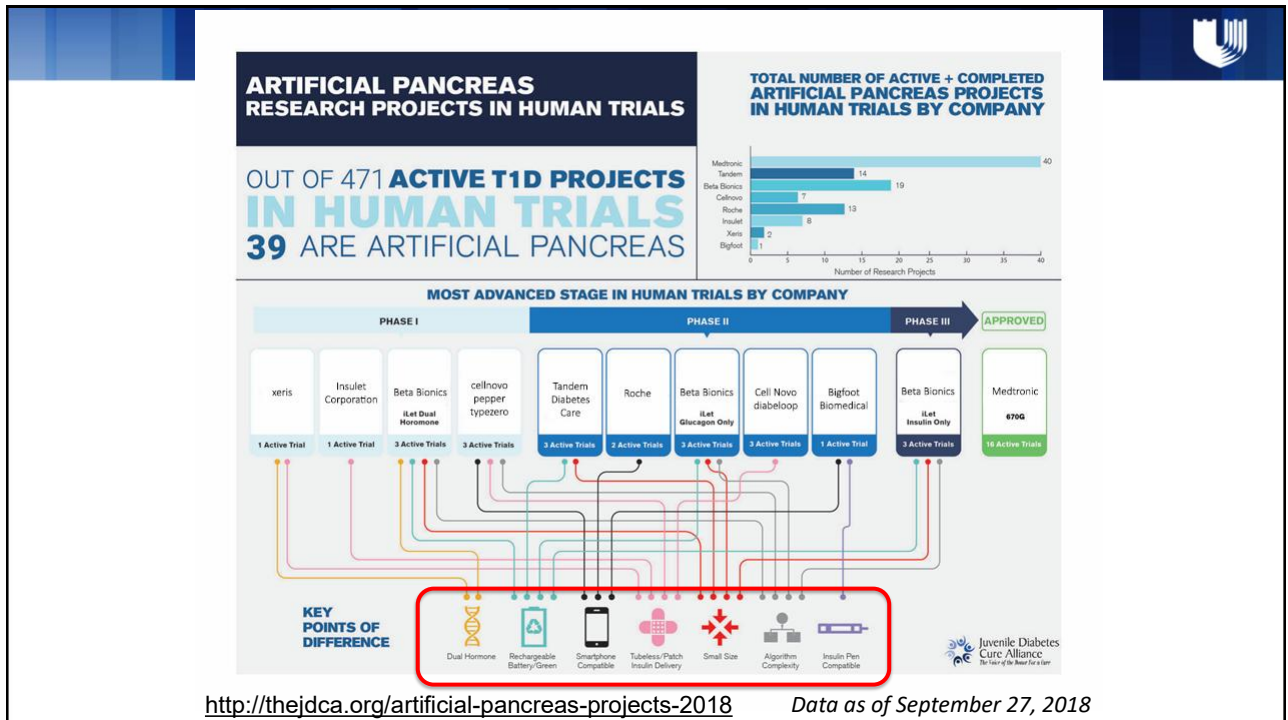


- **Glucagon should reduce risk hypoglycemia, but**
  - Adds device complexity (separate reservoirs, infusion sets)
  - Glucagon stability issues
- **Bihormonal AP reduced risk hypoglycemia overall and during exercise** compared to insulin-only AP
  - Review of 6 trials
  - Additional study needed: trials limited in size, duration
- **Companies working toward device availability**
  - e.g. Beta Bionics, SFC Fluidics in US; Inreda Diabetic B.V. in the Netherlands



Taleb et al. Diabetes Obes Metab 2017; 19(1):13–23  
Taleb et al. DIABETES TECHNOLOGY & THERAPEUTICS Volume 19, Number 10, 2017  
Peters et al. Diabet. Med. 35, 450–459 (2018)

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## What's Ongoing

### NIDDK has funded numerous AP projects

- International Diabetes Closed-Loop Trial (iDCL)
  - Multiple CL protocols
- Day and Night (DAN) CL in Young People with T1DM
  - Up to 150 youth; APS using smartphone as a component
- Fuzzy Logic Automated Insulin Regulation (FLAIR)
  - >100 youth; compares PID control hybrid APS to PID plus fuzzy logic APS to further improve prandial glycemic control
- Bionic pancreas system
  - Single, dual hormonal capabilities

<https://www.nih.gov/news-events/news-releases/four-pivotal-nih-funded-artificial-pancreas-research-efforts-begin>

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## Bionic Pancreas System



- The iLet Bionic Pancreas system has received FDA clearance for use in patients aged 6 and older with T1DM
- Combines the iLet ACE pump with Dosing Decision Software and are paired with a CGM
- Only system that determines 100% of all insulin doses
- To start, just enter body weight
- Meal announcement feature = meals are small, medium, or large –carb counting not required

<https://www.bu.edu/articles/2023/fda-clears-bionic-pancreas-for-type-1-diabetes/>

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## iLet Bionic Pancreas System



<https://www.bu.edu/articles/2023/fda-clears-bionic-pancreas-for-type-1-diabetes/>

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## Telehealth in T2DM Management



Some evidence of improved patient satisfaction, glycemic outcomes

Type of Service	What is the service?	HCP/CS/CPT Code	Patient Relationship with Provider
<b>Medicare Telehealth Visits</b>	Visit with provider uses telecommunication systems between provider and patient	-99201-99215 (office) G0425-G0427 (telehealth consultations, ED, initial patients) G0406-G0408 (follow up inpatient telehealth consultations)	For new or established patients
<b>Virtual Check-In</b>	A brief (5-10 min) check in with practitioner via telephone or telecom. to decide if office visit or service is needed. Remote evaluation of recorded video and/or images submitted by an established patient	HCP/CS code G2012 HCP/CS code G2010	For established patients
<b>E-Visits</b>	A communication between a patient and their provider through an online patient portal	-99421 -99422 -G2061 -G2062 -G2063	For established patients

Grant AK, Golden L. Technological Advancements in the Management of Type 2 Diabetes. Curr Diab Rep. 2019 Dec 20;19(12):163. doi: 10.1007/s11892-019-1278-3. PMID: 31863200.

<https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet>

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## Other Technologies in T2DM Management



- **Glucose Meters that sync with Apps**
  - Dario Health SmartMeter, One TouchVerio, Flex, Accu-chek Aviva Connect Meter, and Contour Next One Smart Meter
- **Educational and remote support services**
  - with glucose meter use (One Drop and Livongo)
- **Wellness Apps and Devices**
  - MyFitnessPal, Loselt, Fitbit, AppleWatch



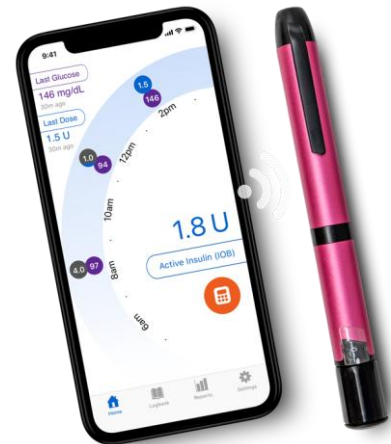
Grant AK, Golden L. Technological Advancements in the Management of Type 2 Diabetes. Curr Diab Rep. 2019 Dec 20;19(12):163. doi: 10.1007/s11892-019-1278-3. PMID: 31863200.

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## Smart Insulin Pens



- Can track timing, dosing, and administration of short-acting mealtime insulin
- Can dispense “standing” doses of mealtime insulin
- Have dosing memory
- Contain bolus-dose calculators that can provide insulin dose recommendations for patients who are carb counting
- Link to cellphone apps and exportable logbooks/reports
- Option of smart pen caps that integrate with CGM system to recommend insulin dose in real time



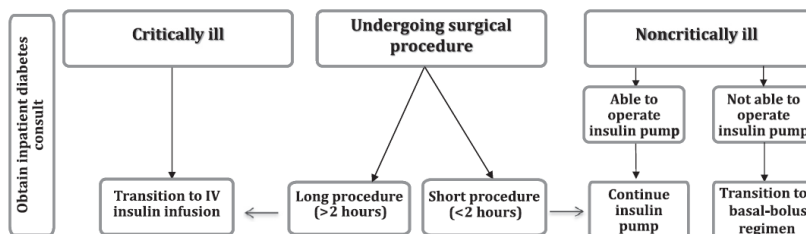
Grant AK, Golden L. Technological Advancements in the Management of Type 2 Diabetes. Curr Diab Rep. 2019 Dec 20;19(12):163. doi: 10.1007/s11892-019-1278-3. PMID: 31863200.

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## Insulin Pumps in the Hospital



### Patient With Insulin Pump Admitted to Hospital



### Changes to Pump Therapy With Imaging Studies

X-ray/CT	Pump should be covered by lead apron
MRI	Pump and metal infusion set should be removed
Ultrasound	No need to remove pump but transducer should not be pointed directly at the pump
Cardiac catheterization	Pump should be covered by lead apron
Pacemaker/automatic implantable cardioverter defibrillator (AICD)	Pump should be covered by lead apron
Colonoscopy/EGD	Pump can remain in place
Laser surgery	Pump can remain in place

Umplierrez GE, Klonoff DC. Diabetes Technology Update: Use of Insulin Pumps and Continuous Glucose Monitoring in the Hospital. Diabetes Care. 2018 Aug;41(8):1579-1589. doi: 10.2337/dci18-0002. Epub 2018 Jun 23. PMID: 29936424; PMCID: PMC6054505.

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## Contraindications to Insulin Pump Use in Hospital



- Impaired level of consciousness (except during short-term anesthesia)
- Patient's inability to correctly demonstrate appropriate pump settings
- Critical illness requiring intensive care
- Psychiatric illness that interferes with a patient's ability to self-manage diabetes
  - Including patients at risk for suicide
- Diabetic ketoacidosis and hyperosmolar hyperglycemic state
- Refusal or unwillingness to participate in self-care
- Lack of pump supplies
- Lack of trained health care providers, diabetes educators, or diabetes specialist
- Health care decision

Umptierrez GE, Klonoff DC. Diabetes Technology Update: Use of Insulin Pumps and Continuous Glucose Monitoring in the Hospital. *Diabetes Care*. 2018 Aug;41(8):1579-1589. doi: 10.2337/dci18-0002. Epub 2018 Jun 23. PMID: 29936424; PMCID: PMC6054505.

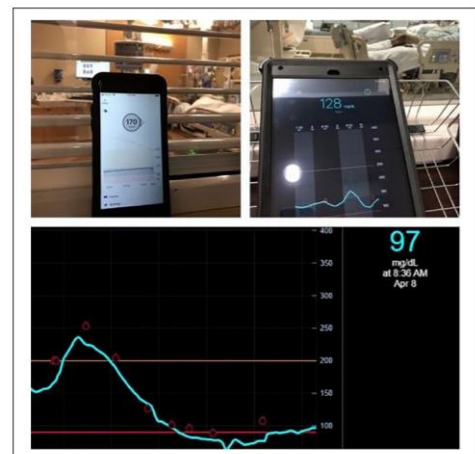
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## CGM Use in Hospital During COVID



### Small Pilot Study

CGM use in “critically ill patients with COVID-19 in the ICU proved to be feasible, reliable, and accurate for real-time glucose trending and as an adjunct to POC-BG to reduce HCP exposure and PPE use during this pandemic.”



Sadhu AR et al. Continuous Glucose Monitoring in Critically Ill Patients With COVID-19: Results of an Emergent Pilot Study. *J Diabetes Sci Technol*. 2020 Nov;14(6):1065-1073. doi: 10.1177/1932296820964264. Epub 2020 Oct 16. PMID: 33063556; PMCID: PMC7645121.

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## In-Hospital Diabetes Management by a Diabetes Team and Insulin Titration Algorithms Based on Continuous Glucose Monitoring or Point-of-Care Glucose Testing in Patients with Type 2 Diabetes (DIATEC): A Randomized Controlled Trial



### Objective

The DIATEC trial investigates the glycemic and clinical effects of inpatient continuous glucose monitoring (CGM)-guided insulin titration by diabetes teams.

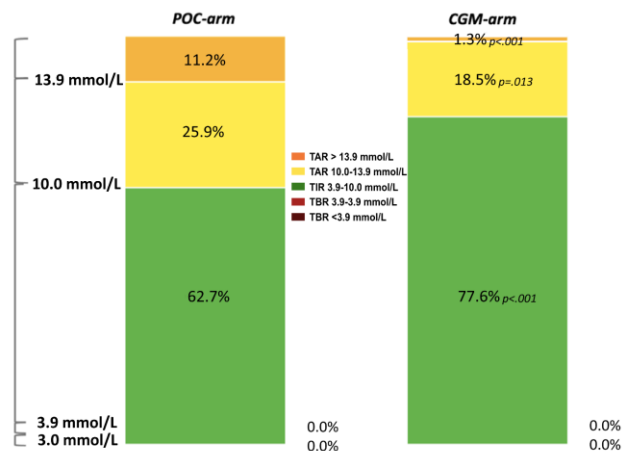
### Methods

This two-center trial randomized 166 non-intensive care unit patients with type 2 diabetes. Diabetes management was performed by regular staff, guided by diabetes teams using insulin titration algorithms based on either point-of-care (POC) glucose testing or CGM. The primary outcome was the difference in time in range (TIR) (3.9–10.0 mmol/L) between the two arms.

### Conclusions

In-hospital CGM increased TIR by a clinically significant 15%-points, mainly by reducing time above range (TAR). CGM also lowered time below range (TBR), glycemic variability, prolonged hypoglycemic events, insulin usage, and in-hospital complications.

### Results



DIATEC, Diabetes Team and CGM in Managing Hospitalized Patients With Diabetes.

Diabetes Care. 2025;48(4):569-578. doi:10.2337/dc24-2222

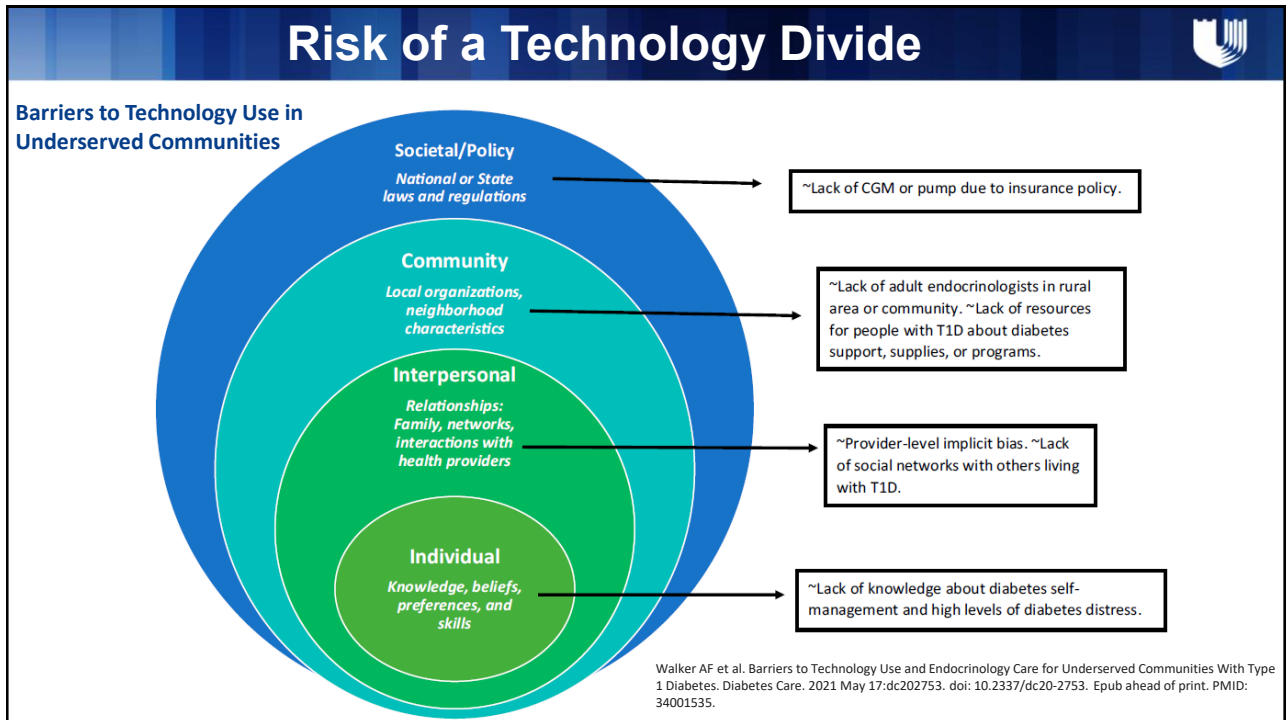
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## Work Still Needed



- **Enhanced user acceptance**
  - Reduced user burden and increased trust
- **Real-world experience**
  - Role for registries, other RWE databases
- **More info re: use in under-studied populations and settings**
- **Prescriber, insurer acceptance**

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## Patient Case #3

58-year-old man with T2DM and obesity

- Current medications:
  - metformin 1000 mg BID
  - Insulin glargine 80 units daily
- Weight 250 lbs; BMI = 38
- BP: 145/92
- He reports fasting glucose of 130 -140 mg/dl but glucose is often >250 later in the day
- A1c = 8.0%

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## Patient Case #3

### AGP Report

Name \_\_\_\_\_

MRN \_\_\_\_\_

#### GLUCOSE STATISTICS AND TARGETS

**26 Feb 2019-10 Mar 2019**  
**% Time CGM is Active****13 days**  
**99.9%**

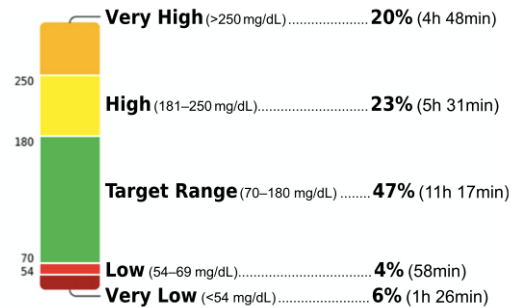
Glucose Ranges	Targets [% of Readings (Time/Day)]
Target Range 70–180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

Each 5% increase in time in range (70–180 mg/dL) is clinically beneficial.

<b>Average Glucose</b>	<b>173 mg/dL</b>
<b>Glucose Management Indicator (GMI)</b>	<b>7.6%</b>
<b>Glucose Variability</b>	<b>49.5%</b>

Defined as percent coefficient of variation (%CV); target ≤36%

#### TIME IN RANGES



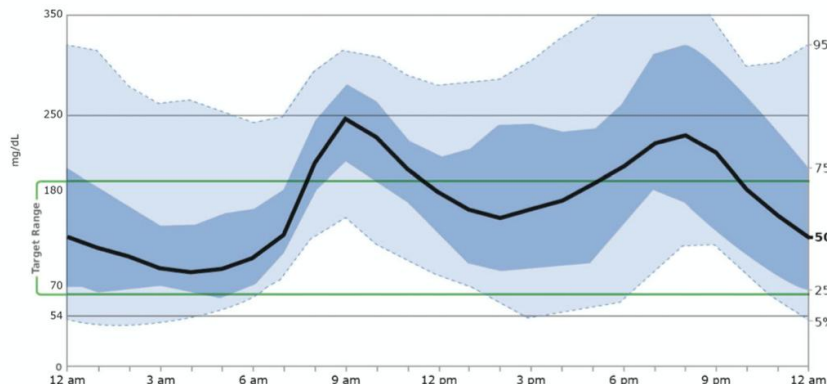
Diabetes Care 2019;42:1593–1603

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## Patient Case #3

#### AMBULATORY GLUCOSE PROFILE (AGP)

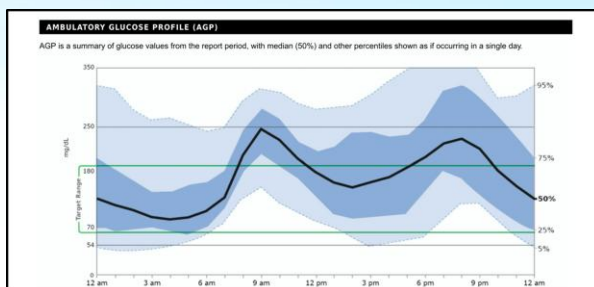
AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.



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## What Is the Next Best Step?

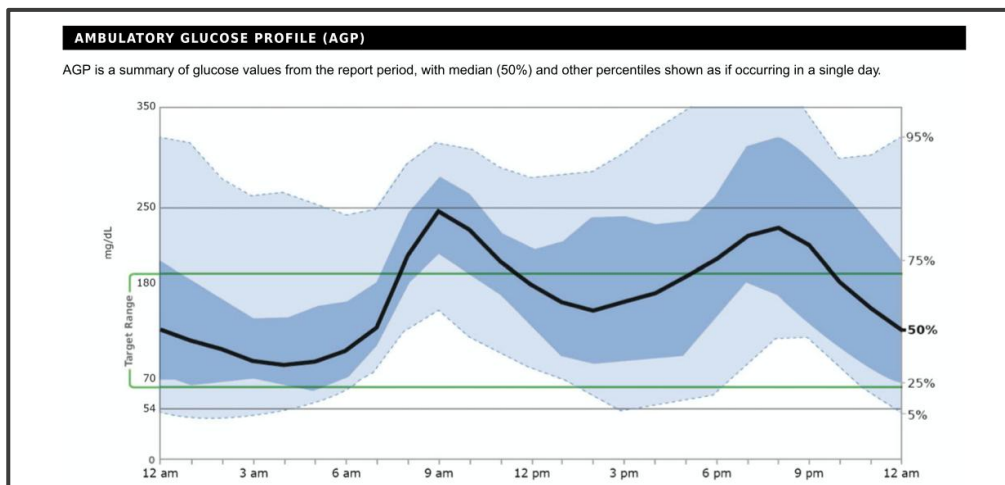


- A. Add mealtime insulin
- B. Add a sulfonylurea
- C. Add a GLP-1 receptor agonist
- D. Decrease insulin glargine dose

## Patient Case #3



Too much basal insulin -> drop in blood sugar overnight



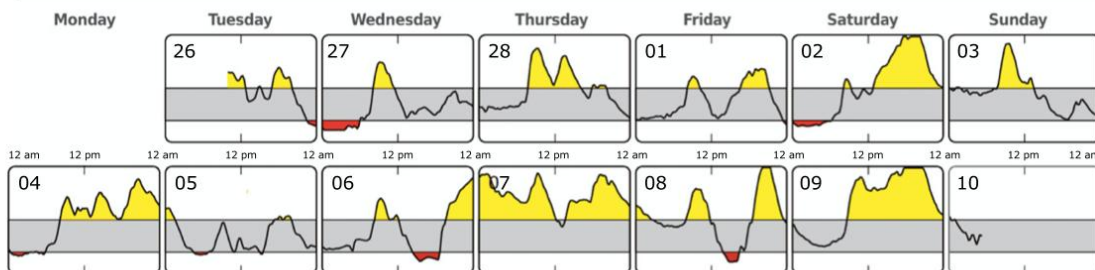
Also having hyperglycemia after meals – but address hypoglycemia first!

## Patient Case #3



### Over-basalization

#### DAILY GLUCOSE PROFILES



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

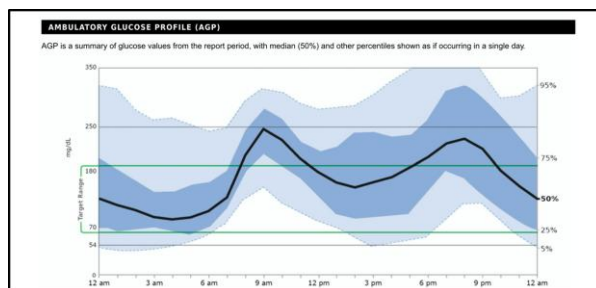
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## Patient Case #3



### What is the next best step?

- A. Add mealtime insulin
- B. Add a sulfonylurea
- C. Add a GLP-1 receptor agonist
- D. Decrease insulin glargine dose



**Decrease insulin glargine to eliminate lows, then reevaluate and add GLP-1RA if still high after meals (likely)**

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