Diabetes Technology and Beyond

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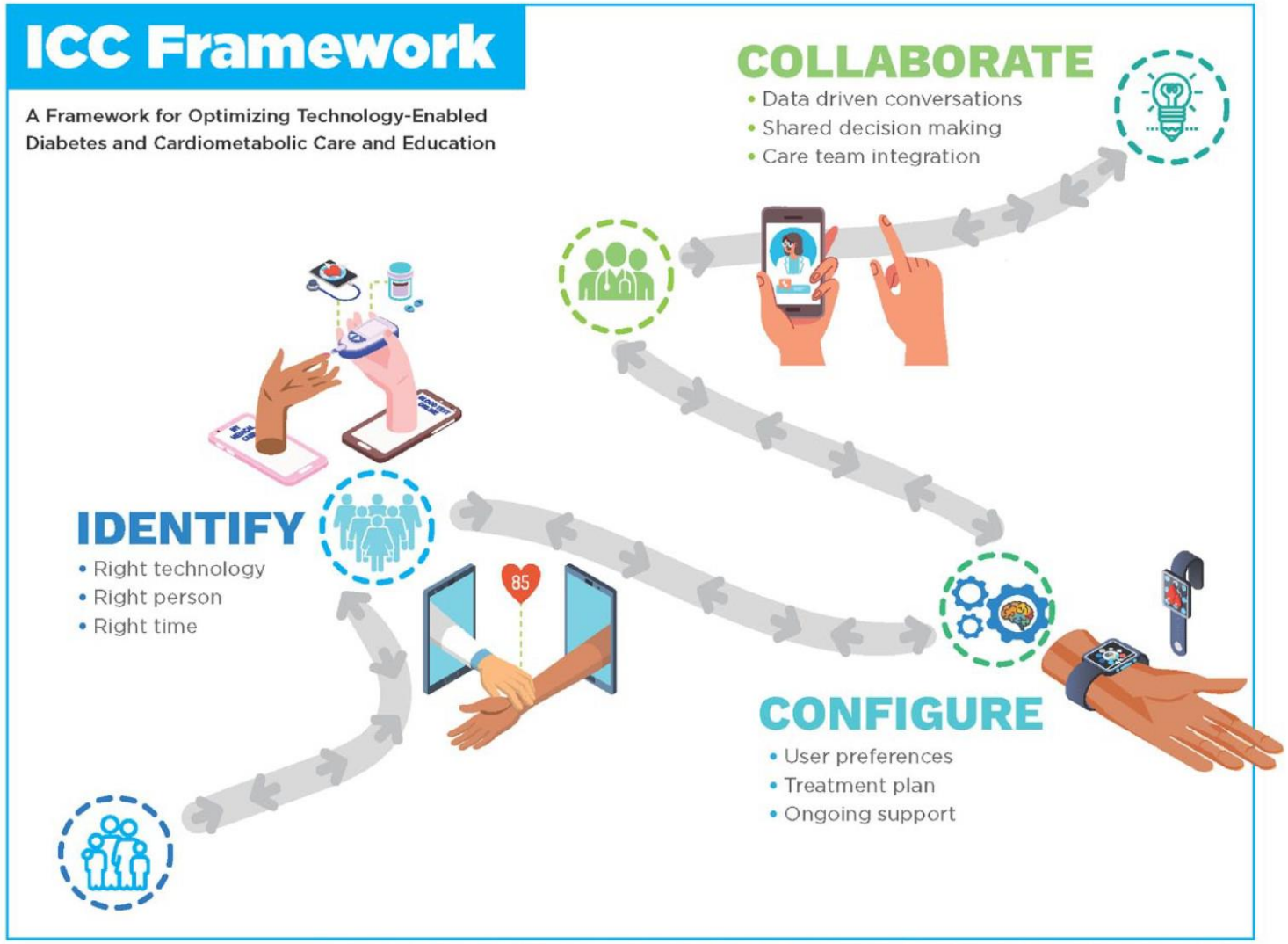
Learning Objectives

- Discuss continuous glucose monitoring (CGM) and the clinical benefits for managing diabetes
- Describe critical teaching content for insulin pump and CGM use
- Compare and contrast the CGM, connected pen and insulin pump devices
- Describe appropriate candidates for insulin pump therapy
- List inpatient considerations for insulin pump therapy and CGMs

ICC Framework – Identify-Configure-Collaborate

A framework to overcome barriers to technology use and therapeutic inertia



Greenwood DA, Howell F, Scher L, et al. A Framework for Optimizing Technology-Enabled Diabetes and Cardiometabolic Care and Education: The Role of the Diabetes Care and Education Specialist. The Diabetes Educator. 2020;46(4):315-322. doi:10.1177/0145721720935125

Technology is Here

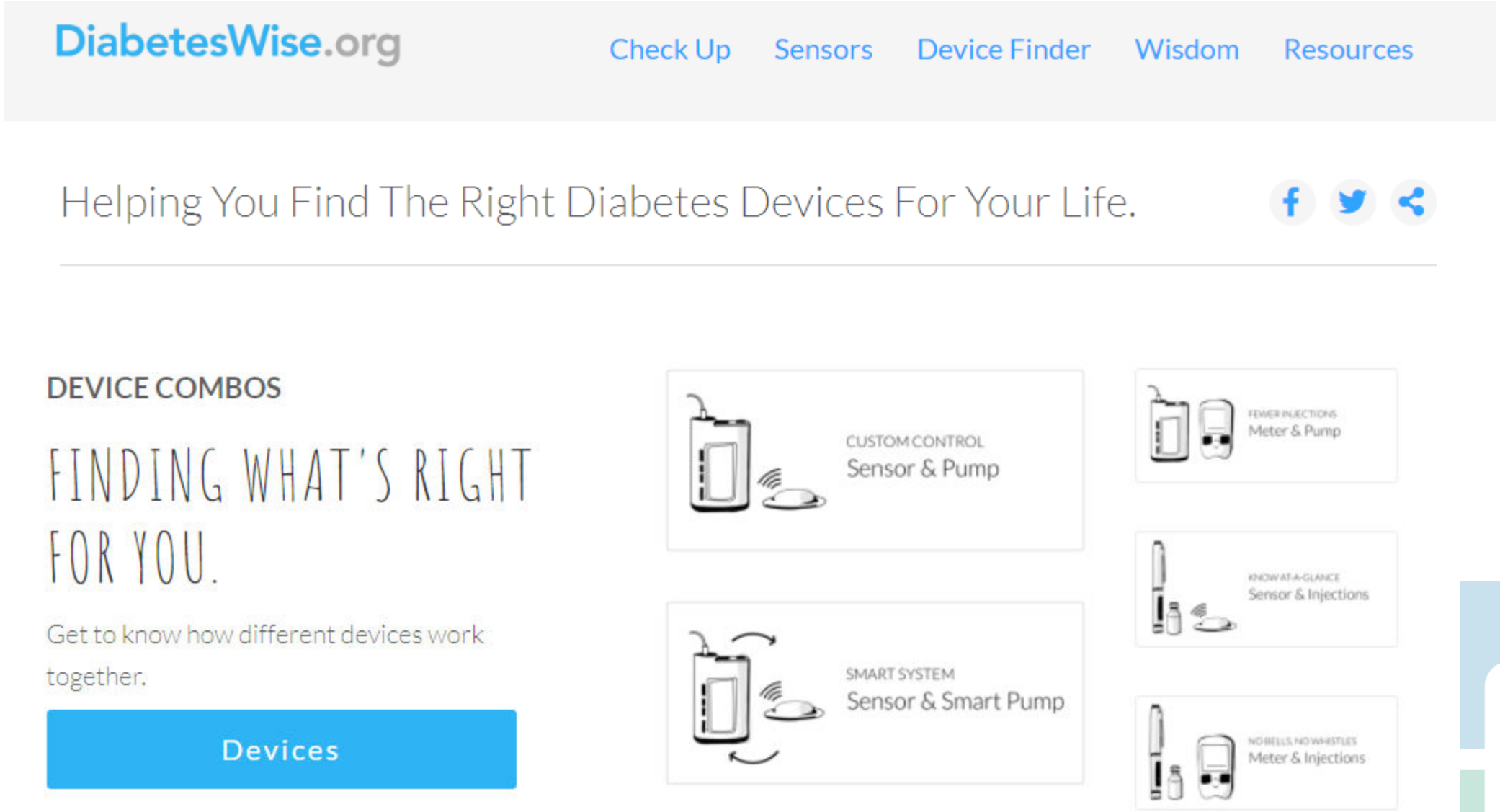
CONTINUOUS GLUCOSE MONITORS (CGM)

INSULIN PUMPS

CONNECTED PENS AND CAPS

MOBILE APPS

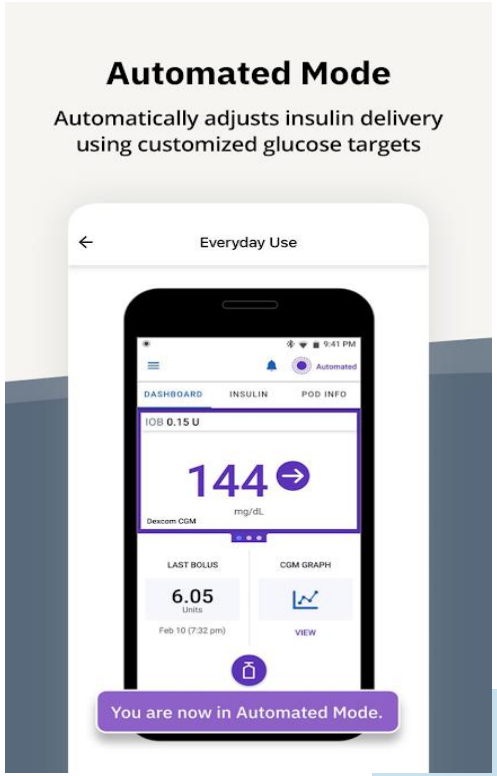
Identify: PWD Identify the “Right” Technology



Diabeteswise.org, providers.diabeteswise.org/#/

Simulation Apps to Test it Out

Tandem Simulator



Omnipod Simulation app

The Importance of Education & Training

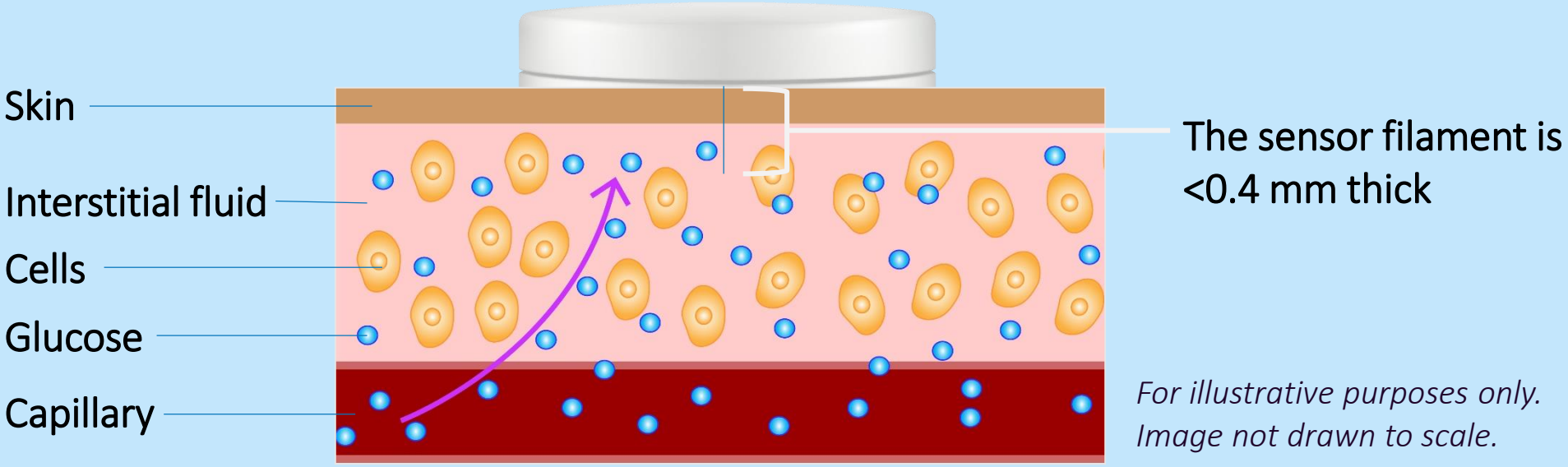
"No device used in diabetes management works optimally without education, training, and follow-up."

ADA. Diabetes Care. 2022;45:S1.

Continuous Glucose Monitors

Continuous Glucose Monitors (CGM)

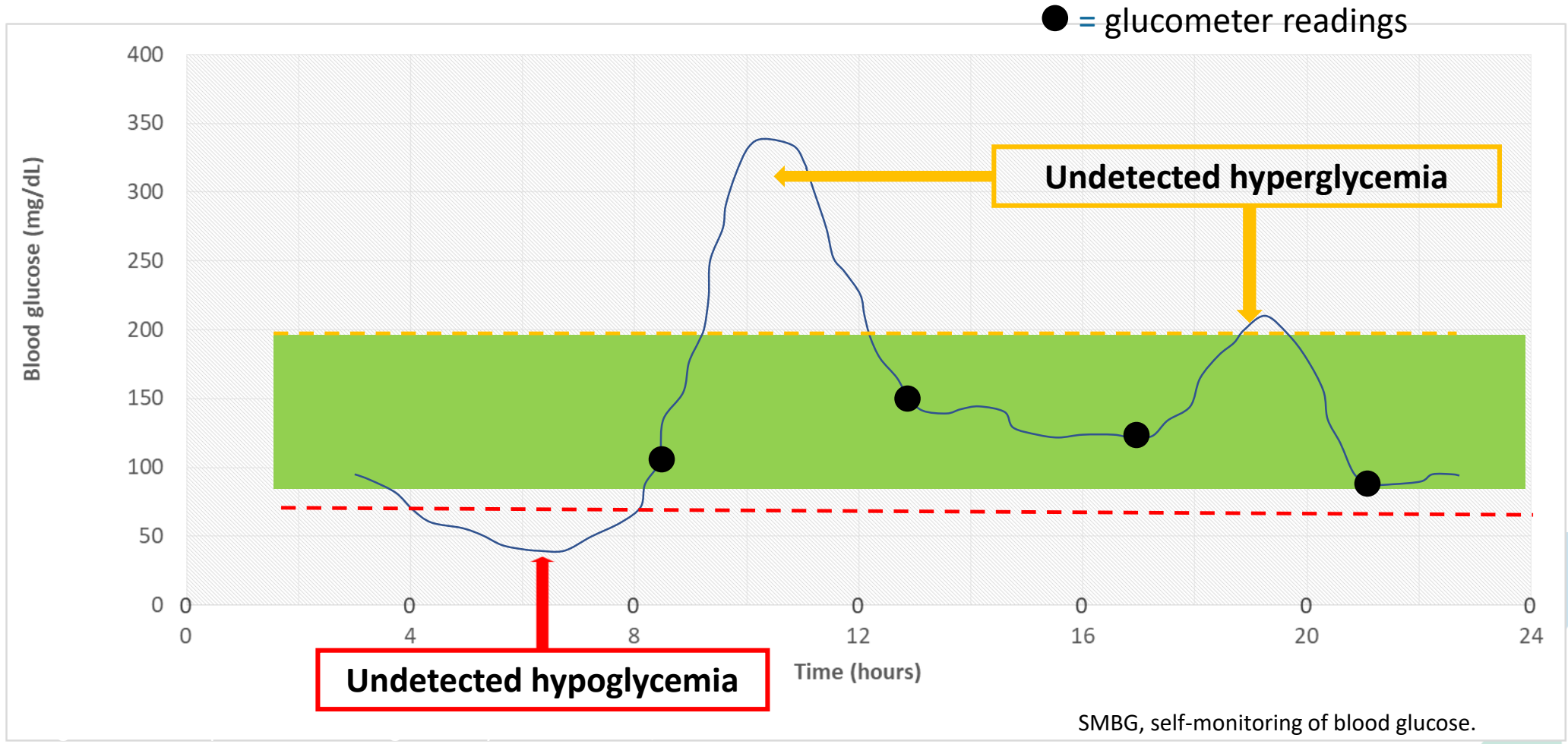
- Measures glucose (sugar) every 1-5 mins and records it every 5-15 mins (up to 288 readings/day)
- Includes 3 components: transmitter, sensor, receiver/reader



For illustrative purposes only.
Image not drawn to scale.

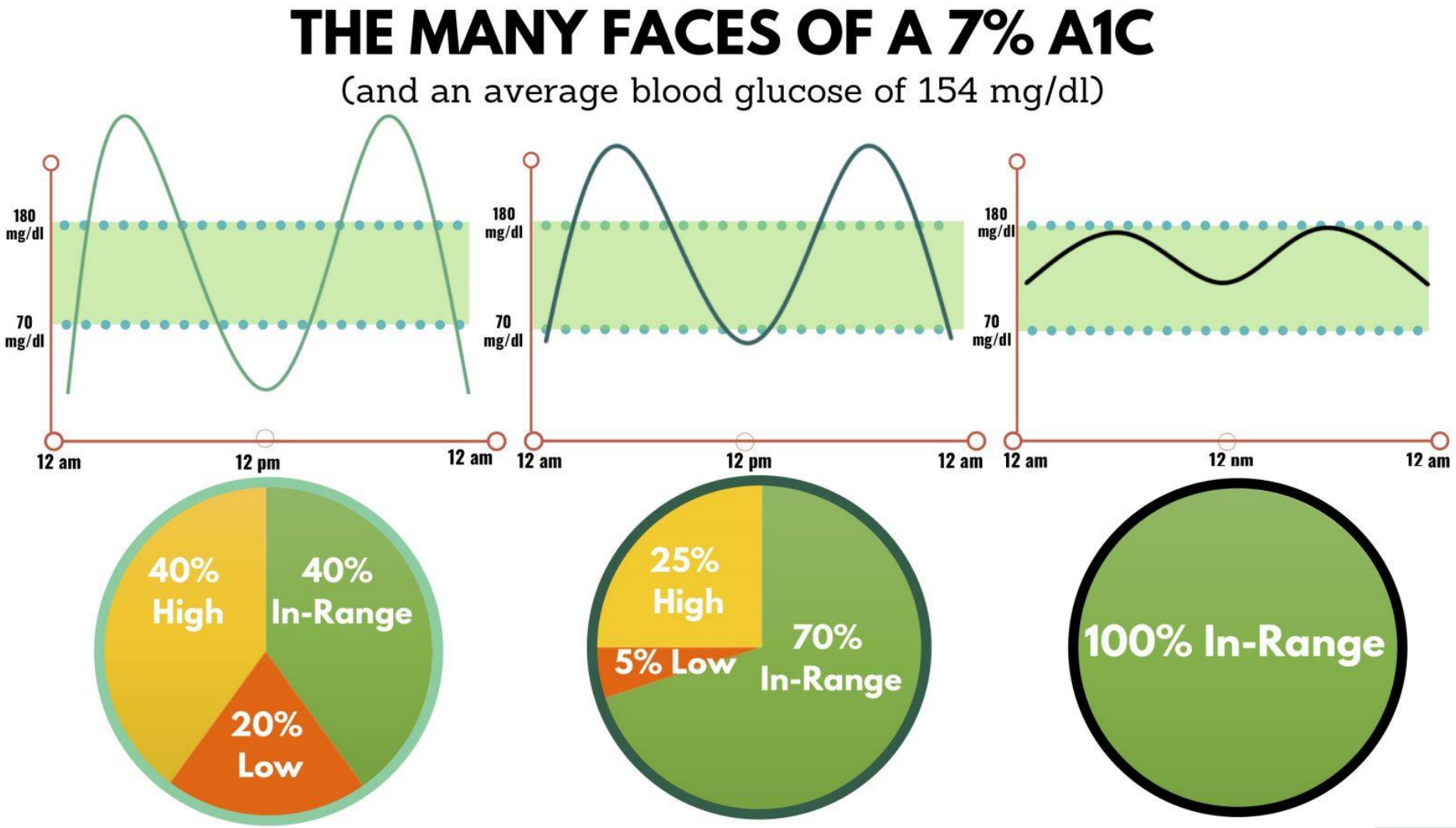
Illustration adapted from: Association of Diabetes Care & Education Specialists. ADCES Practice Paper. Accessed 11/9/21. https://www.diabeteseducator.org/docs/default-source/practice/practice-documents/practice-papers/the-diabetes-educator-role-in-continuous-glucose-monitoring.pdf?sfvrsn=4

BGM vs CGM

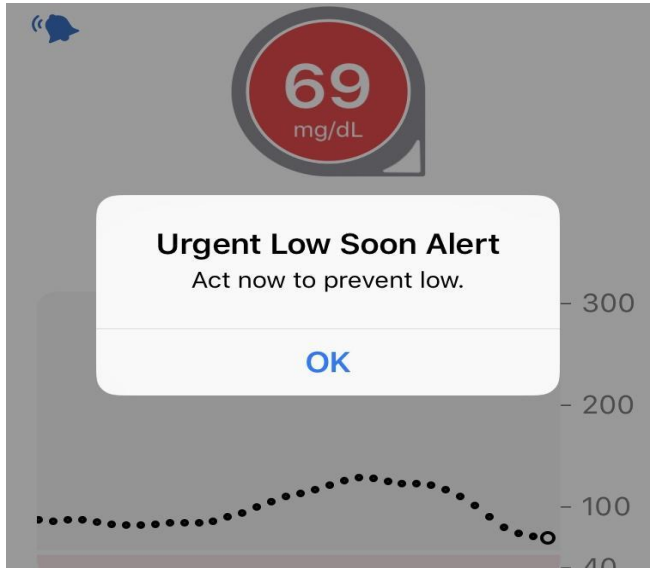


SMBG, self-monitoring of blood glucose.

A1C Alone is Just Not Enough



CGM: Real-Time Data



Types of CGM

Professional	Personal
Owned by the clinic	Owned by the person with diabetes
Blinded and unblinded (real-time feedback) options	Real-time feedback or scan for feedback (flash device)
Short-term use (3-14 days)	Long-term use
Insurance coverage for most people with type 1 or type 2 diabetes	Insurance coverage more focused on type 1 diabetes or those on intensive insulin regimens
Not compatible with insulin pumps or connected pens	Compatible with smartphones, connected pens and insulin pumps with select devices

Wright LA, Hirsch IB. *Diabetes Technol Ther.* 2017;19(suppl 2):S16-S26; Kruger DF, et al. *Diab Educ*. 2019;45(suppl 1):S3-S20.

Professional CGM Options

Abbott FreeStyle Libre Pro

Dexcom G6 Pro

Professional CGM Comparison

	Dexcom G6 Pro	LibrePro
Blinded vs unblinded	Both	Blinded
Maximum wear time of sensor	10 days	14 days
Calibration	None	None
Downloading reports	Clarity	LibreView
Care between transmitter use	Disposable-1 time use, must attached transmitter	Disposable 1-time use, combined sensors/transmitter
Alarms for high/low glucose alerts	Yes	No
Interfering substances	Hydroxyurea	Salicylic acid and high-dose vitamin C

ADCES Practice Paper. The diabetes care and education specialist role in CGM.

Personal CGM Products

Freestyle Libre 2
Freestyle Libre 3
Dexcom G6
Dexcom G7
Eversense 180 day
Guardian Connect & Guardian 3

Dexcom G6

- 10 day wear
- 2 hour warm-up
- FDA approved ages 2 and over
- No calibrations required-optional
- 1 press inserter, must attach transmitter
- Reusable transmitter-3 months
- FDA approved for dosing decisions
- Choice of receiver or smart phone
- High, low, predictive low alert
- Hydroxyurea drug interference
- Dexcom G6, Clarity, and Dexcom follow apps (up to 10 followers)
- iCGM Status

https://www.dexcom.com/g6-cgm-system

Inserting the G6 Sensor

Dexcom G7

- 10.5 day wear
- 30 minute warm-up
- FDA approved ages 2 and over
- No calibrations required-optional
- Fully disposable
- No more separate transmitter
- FDA approved for dosing decisions
- Choice of receiver or smart phone
- More customization with alerts
- Hydroxyurea drug interference
- Dexcom G7, Clarity, and Dexcom follow apps (up to 10 followers)
- iCGM Status

https://www.dexcom.com/g6-cgm-system

Inserting the G7 Sensor

Guardian Connect and Guardian 3

- 7 day wear
- Up to 2 hour warm-up
- Not FDA approved for dosing decisions
- Calibrations required 2-4 times/day
- Acetaminophen and Hydroxyurea interference
- Guardian 3 sensor –compatible with 670G and 770G inulin pumps
- Guardian Connect- compatible with smart phone (no separate receiver)
- Reusable transmitter
  - Charge every 7 days, transmitter lasts for ~1 year
- Carelink Connect Mobile app for 770G users
- Ability to have followers

https://www.medtronicdiabetes.com/products/guardian-connect-continuous-glucose-monitoring-system

Inserting the Guardian Sensor

Freestyle Libre 2

- 14 day wear
- 1 hour warm-up
- FDA approved ages ≥ 4 years
- Real time alerts (hypo, hyper, out of range) - must scan for actual number
- FDA approved for insulin dosing except for the first 12 hours after insertion
- Must scan every 8 hours to avoid data gaps
- Vitamin C interference (>500mg)
- 1 press inserter, disposable transmitter included with sensor
- Libre2 mobile app, required alert when glucose is urgent low (55mg/dL)
- LibreLinkUp allows up to 20 followers
- iCGM status

https://www.freestylelibre.us/safety-information.html

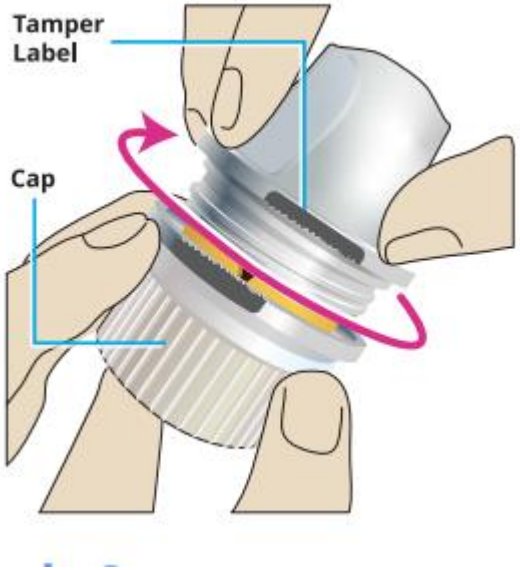
Inserting the Libre 2

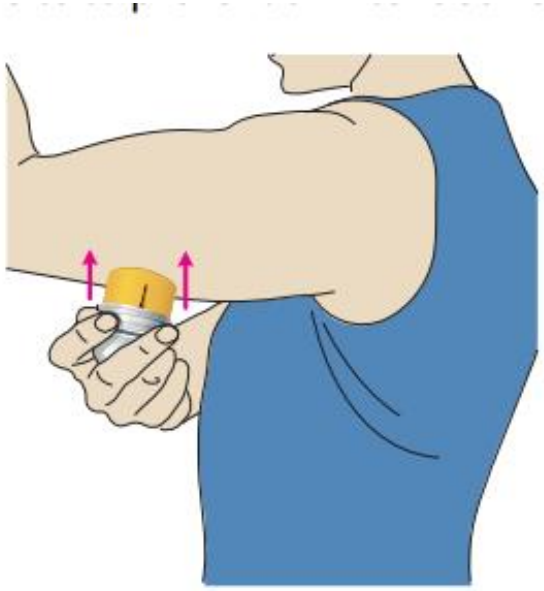
Freestyle Libre 3

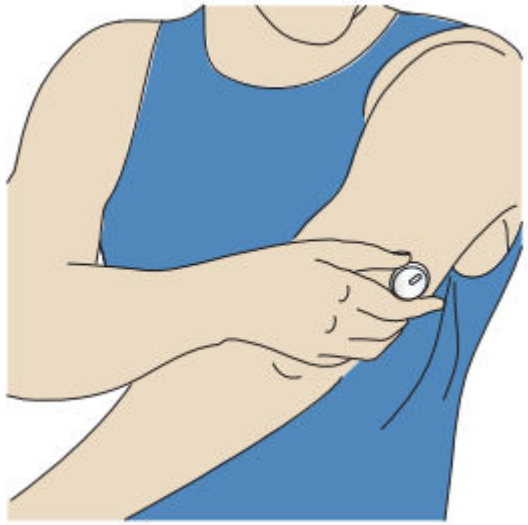
- FDA Approved May 31, 2022
- 14 day wear, 1 hour warm-up, >4 years
- Improvements:
  - No scanning required, 33 foot range
  - Continuous streaming (no gaps in data)
  - Decreased size (2/3 the size of Libre 2)
  - Records user views of data
  - Easier insertion
- Differences:
  - Only compatible with smartphones (no reader-yet)

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

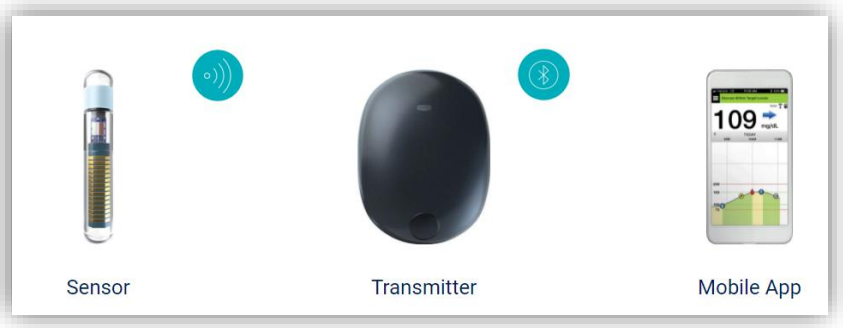
Inserting the Libre 3







Eversense



- Implantable CGM sensor – lasts 180 days
  - Sensor is MRI safe
- Removable, rechargeable transmitter
  - Taped above sensor
  - Communicates to smartphone (no separate receiver)
  - On-body vibe high and low glucose alerts
- FDA-approved for insulin dosing
- 24-hour warm-up (dressing for 2 days after insert)
- Requires calibrations every 12 hours x 3 weeks
- Then 1 calibration/day
- Eversense CGM Mobile app with predictive alerts
- Eversense Now app allows 5 followers

https://www.eversensediabetes.com/

Personal CGM Comparison

	G6	G7	Libre 2	Libre 3	Guardian	Eversense
Integration	T:Slim X2, Omnipod 5, InPen	No	Bigfoot Unity	No	770G, InPen	No
Display device	Smartphone or receiver		Smart phone or reader	Smartphone only	Smartphone or insulin pump	Smartphone only
Maximum wear time	10 days	10.5 days	14 days	14 days	7 days	180 days
Warm-up time	2 hours	30 min	1 hour	1 hour	Up to 2 hours	24 hours
Calibrations required	0	0	0	0	At least 2/day	2/day for 21 days, then 1/day
FDA approved sites	Abdomen (ages 2+) Upper buttocks (ages 2-17)	Upper arm (ages 7+) Upper buttocks (ages 2-6)	Upper arm	Upper arm	Upper arm, abdomen Upper buttocks (ages 7-13)	Upper arm
FDA approved for dosing	Yes	Yes	Yes	Yes	No	Yes
FDA Approved ages (years)	≥2	≥2	≥4	≥4	≥2 Guardian 3 ≥14 Guardian Connect	≥18
Drug Interactions	Hydroxyurea	Hydroxyurea	Vitamin C	Vitamin C	Acetaminophen, Hydroxyurea	Tetracycline antibiotics, mannitol
MARD	9%	8.2%	9.2%	7.9%	9.64%	8.5%
Alarms	High, Low, Predictive Low		High, Low	High, Low,	High, Low, Predictive	High, Low, Predictive

Product user guides: Dexcom G6, Dexcom G7, Libre 2, Libre 3, Medtronic Guardian Connect, Guardian 3, Eversense

Poll Question

Which of the following drugs interact with the Libre systems?

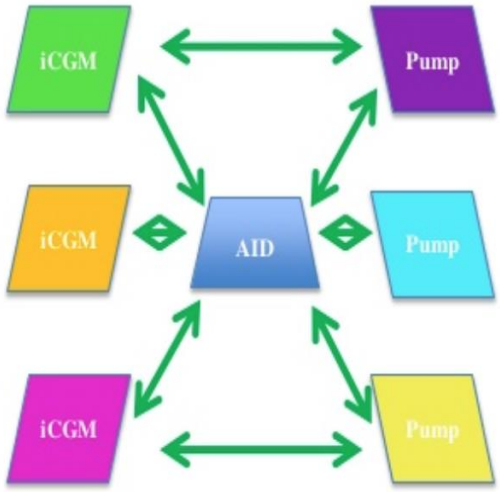
A. Aspirin
B. Vitamin C
C. Hydroxyurea
D. Acetaminophen

iCGM: The Future of Diabetes Devices

- Dexcom G6 and Libre 2 are integrated CGM (iCGM)

- Integration with digitally connected devices (eg, pumps, pens, automated insulin dosing [AID] systems)

Goal: Greater Interchangeability



- More efficient regulatory pathways
- Faster innovation
- A more vibrant device ecosystem

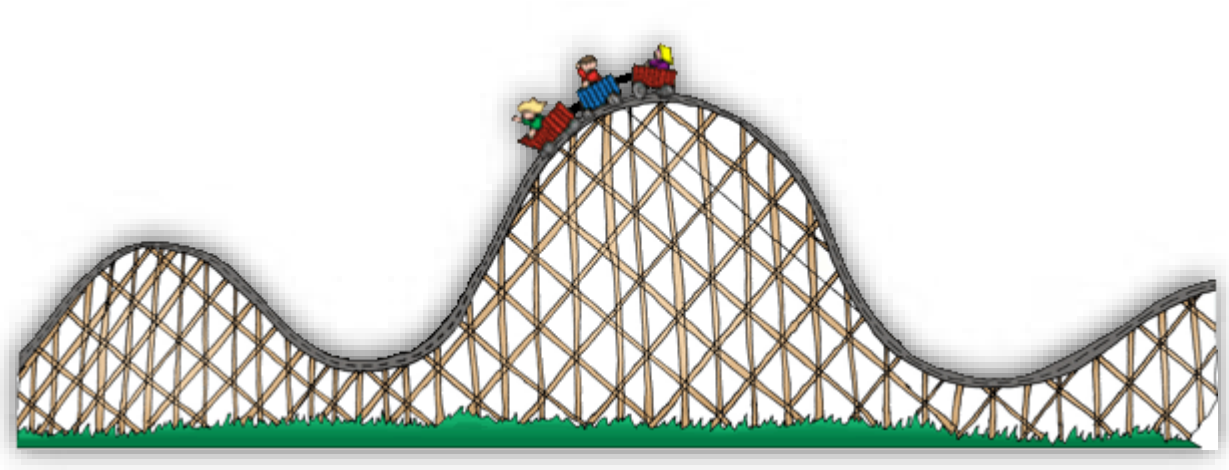
CGM Counseling Points

- Important to check glucose when indicated
  - Symptoms do not match sensor value
  - During warm-up period
  - When making dosing decisions for select devices
- Sensors are waterproof
  - Showering, bathing, swimming OK
- Avoid with MRI, CT, diathermy
  - Exception: Eversense implantable, transmitter should be removed
- Not FDA approved
  - Dialysis, critically ill
  - Pregnancy-Guardian, eversense, G6
  - If people choose to use, it is important they know it is off-label and discuss potential risks

Troubleshooting Site Adhesiveness

Lag Time

- Refers to a delay in CGM sensor readings compared to finger stick blood glucose readings
  - Estimated CGM sensor reading ~5 minutes behind
- Most apparent when glucose is changing rapidly



Downloading CGM Data

At least 42 factors affect glucose!

Food

1. ↑↑ Carbohydrate quantity
2. →↑ Carbohydrate type
3. →↑ Fat
4. →↑ Protein
5. →↑ Caffeine
6. ↓↑ Alcohol
7. ↓↑ Meal timing
8. ↑ Dehydration
9. **?** Personal microbiome

Medication

10. →↓ Dose
11. ↓↑ Timing
12. ↓↑ Interactions
13. ↑↑ Steroid administration
14. ↑ Niacin (vitamin B3)

Activity

15. →↓ Light exercise
16. ↓↑ High/moderate exercise
17. →↓ Level of fitness/training
18. ↓↑ Time of day
19. ↓↑ Food and insulin timing

Biological

20. ↑ Insufficient sleep
21. ↑ Stress and illness
22. ↓ Recent hypoglycemia
23. →↑ During-sleep blood sugars
24. ↑ Dawn phenomenon
25. ↑ Infusion set issues
26. ↑ Scar tissue and lipodystrophy
27. ↓↓ Intramuscular insulin delivery
28. ↑ Allergies
29. ↑ A higher glucose level
30. ↓↑ Menstruation
31. ↑↑ Puberty
32. ↓ Celiac disease
33. ↑ Smoking

Environmental

34. ↑ Expired insulin
35. ↑ Inaccurate BG reading
36. ↓↑ Outside temperature
37. ↑ Sunburn
38. **?** Altitude

Behavioral and decision making

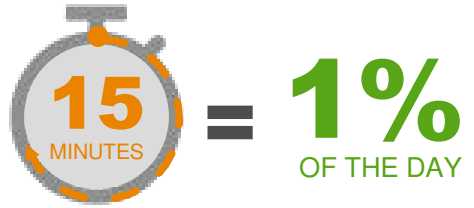
39. ↓ Frequency of glucose checks
40. ↓↑ Default options and choices
41. ↓↑ Decision-making biases
42. ↓↑ Family relationships and social pressures

Adapted from Brown A. DiaTribe Learn: Making sense of diabetes...
diatribe.org/42factors

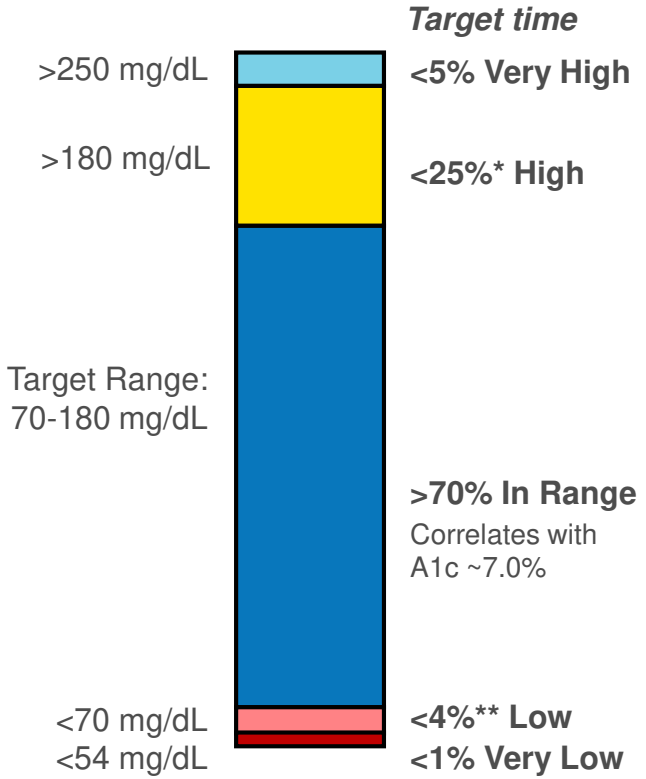
Collaborate: How to Share Data

System:	Associated Mobile Apps	Data Sources
Glooko	Glooko	Insulin pumps (Omnipod, T:slim X2), Dexcom, Eversense, many glucose meters, InPen
Clarity	Dexcom G6, G7, Clarity, Dexcom Follow, Undermyfork, Sugarmate	Dexcom, InPen
LibreView	LibreLink, LibreLinkUp, Libre 14 day, Libre 2, Libre 3	Libre 14 day, Libre 2, Libre 3
Carelink	Guardian Connect, Carelink	770G, Guardian CGM, InPen
Tidepool	Tidepool Mobile	Insulin pumps (770G, T:Slim X2, Tandem, Omnipod), Dexcom, Guardian, Libre, many glucose meters, InPen
T:Connect	T:Connect Mobile	T:Slim X2, G6
Eversense Data Management System	Eversense	Eversense
InPen Insights Report	InPen	InPen, Dexcom, Guardian Connect
Bigfoot Unity	Bigfoot Unity	Bigfoot Unity pen cap, Libre 2
Tempo Platform	TempoSmart	TempoSmart Button, Dexcom

CGM Key Metrics



Recommended Time in Range for most people with T1D & T2D



Time above range (TAR)
< 1 hr, 12 min, > 250 mg/dL
< 6 hr, > 180 mg/dL

Time in range (TIR)
> 16 hr, 48 min

Time below range (TBR)
< 1hr < 70mg/dL
< 15 min < 54mg/dL

Number of days CGM is worn 14 days is recommended
Percentage of time CGM is active 70% of data from 14 days is recommended
Mean glucose
Glucose management indicator (GMI) Estimated A1C
Coefficient of variation (CV) This is a measure of glycemic variability. A CV >36% is considered unstable.

1. Battelino T et al. *Diabetes Care.* 2019;42(8):1593-1603. . 2. American Diabetes Association. *Diabetes Care 2021;44(Suppl. 1):S73–S84 | https://doi.org/10.2337/dc21-S006.*

What is the goal time in range for most adults with type 1 or 2 diabetes?

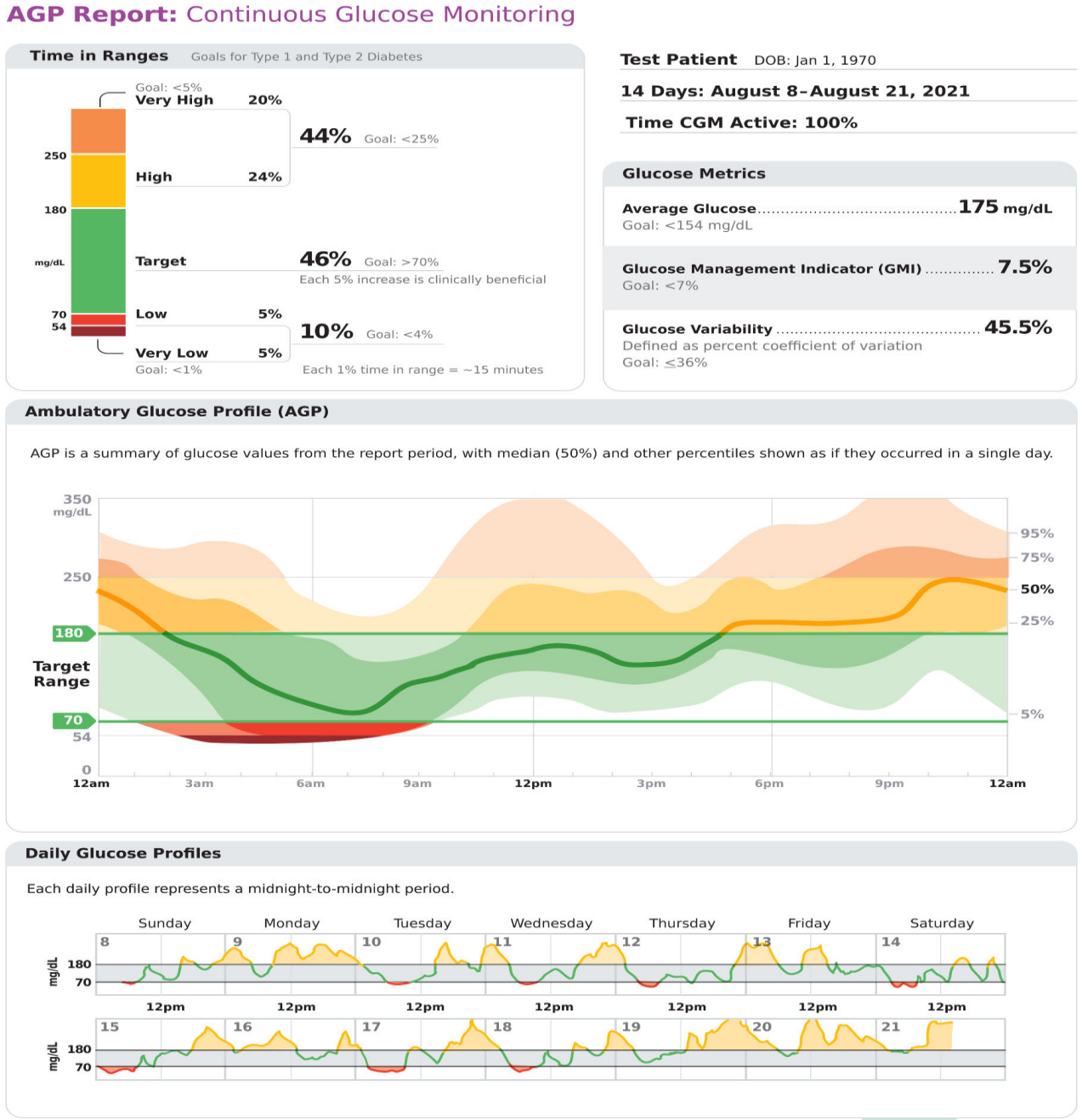
A.≥50%

B.≥70%

C.≥80%

D.≥90%

AGP Report


AGP Report: Continuous Glucose Monitoring
Time in Ranges
Goals for Type 1 and Type 2 Diabetes
Goal: <5%
Very High 20%
44% Goal: <25%
250
High 24%
180
mg/dL
Target 46% Goal: >70%
Each 5% increase is clinically beneficial
70
54
Low 5%
10% Goal: <4%
Very Low 5%
Goal: <1%
Each 1% time in range = ~15 minutes
Test Patient DOB: Jan 1, 1970
14 Days: August 8–August 21, 2021
Time CGM Active: 100%
Glucose Metrics
Average Glucose 175 mg/dL
Goal: <154 mg/dL
Glucose Management Indicator (GMI) 7.5%
Goal: <7%
Glucose Variability 45.5%
Defined as percent coefficient of variation
Goal: ≤36%
Ambulatory Glucose Profile (AGP)
AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if they occurred in a single day.
350
mg/dL
250
180
Target Range
70
54
0
95%
75%
50%
25%
5%
12am
3am
6am
9am
12pm
3pm
6pm
9pm
12am
Daily Glucose Profiles
Each daily profile represents a midnight-to-midnight period.
Sunday
Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
8
9
10
11
12
13
14
mg/dL
180
70
12pm
15
16
17
18
19
20
21

Spaghetti Graph

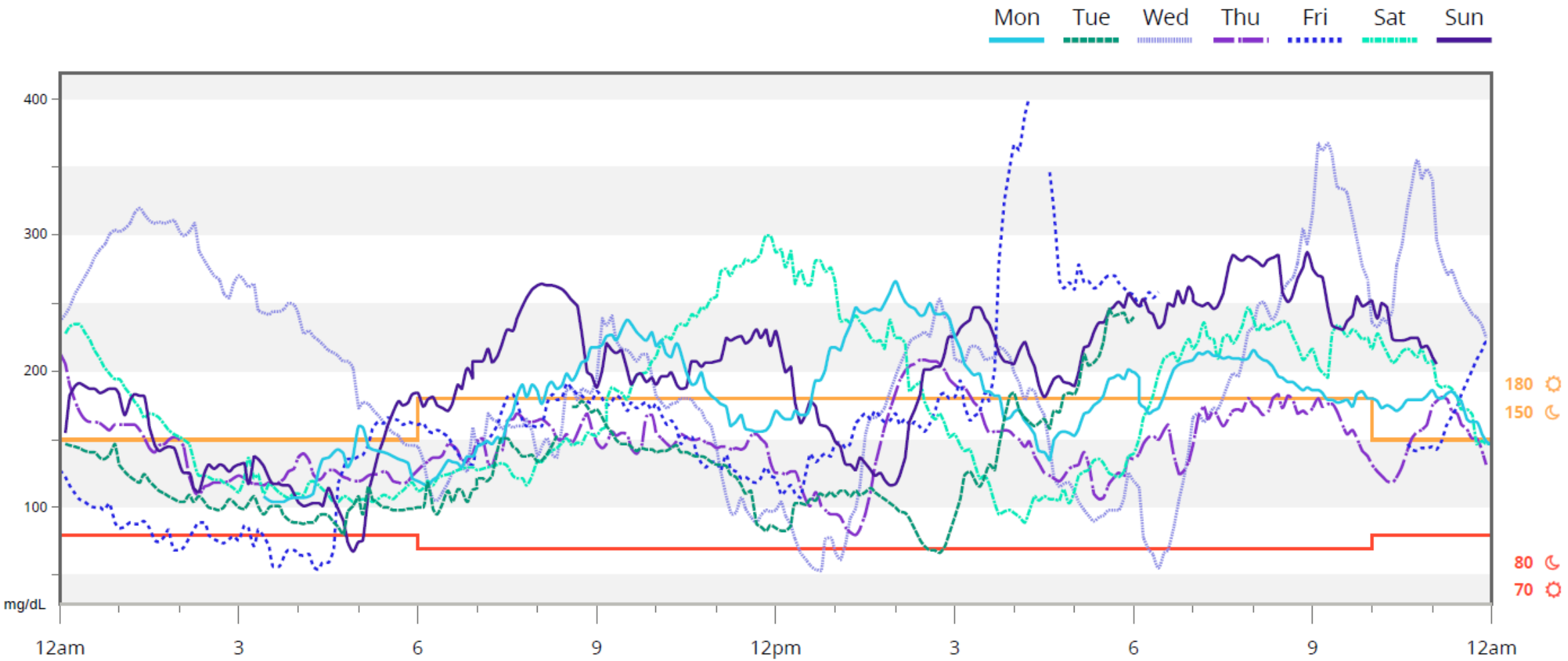
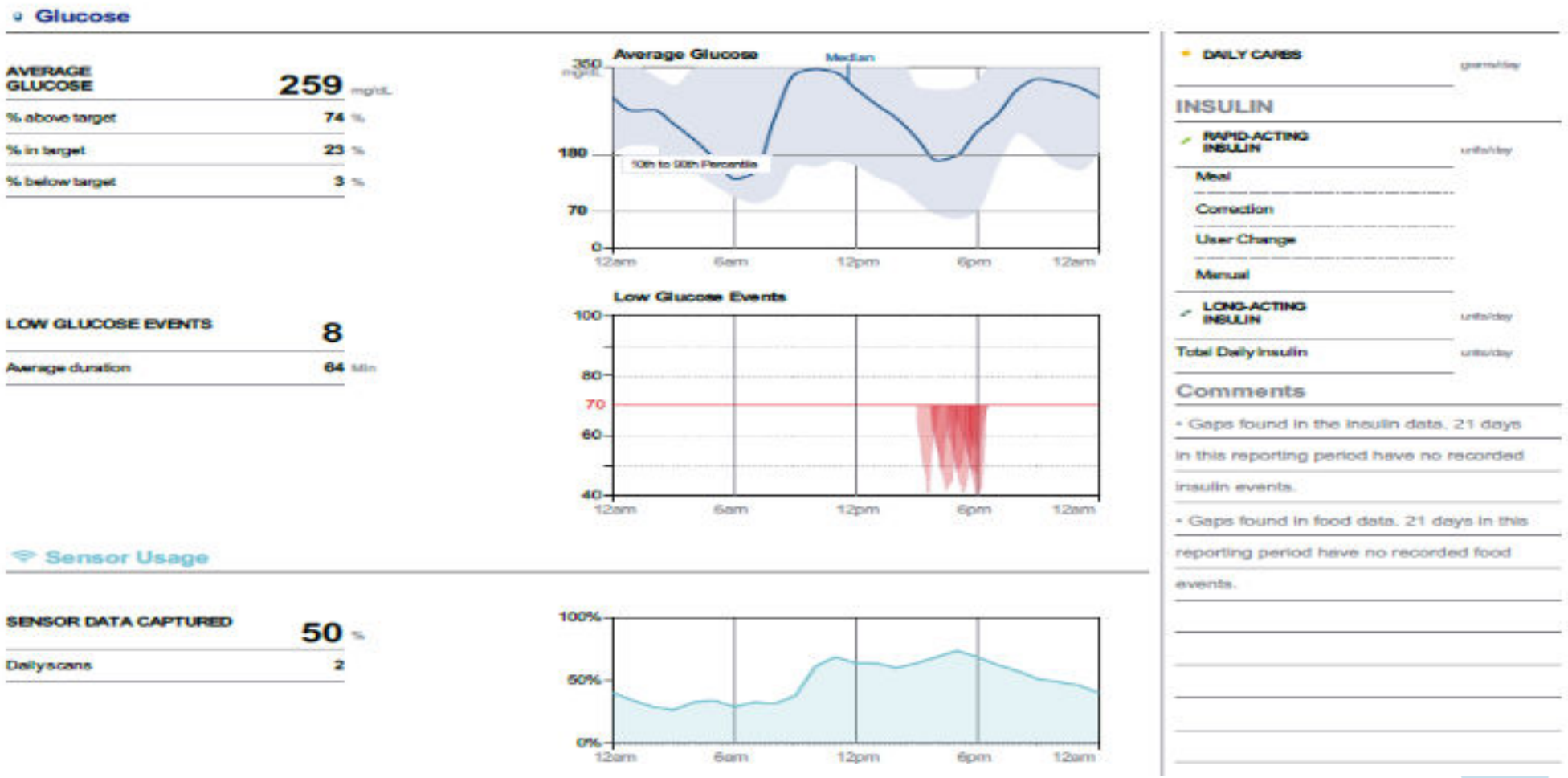


Image obtained from Dexcom CLARITY report.

Snapshot to Assess Hypoglycemia



Glucose

AVERAGE GLUCOSE	259 mg/dL
% above target	74 %
% in target	23 %
% below target	3 %

LOW GLUCOSE EVENTS	8
Average duration	64 Min

Sensor Usage

SENSOR DATA CAPTURED	50 %
Daily scans	2

DAILY CARBS grams/day

INSULIN

RAPID-ACTING INSULIN units/day

- Meal
- Correction
- User Change
- Manual

LONG-ACTING INSULIN units/day

Total Daily Insulin units/day

Comments

- Gaps found in the insulin data. 21 days in this reporting period have no recorded insulin events.
- Gaps found in food data. 21 days in this reporting period have no recorded food events.

Image obtained from LibreView report.

Day by Day Graphs

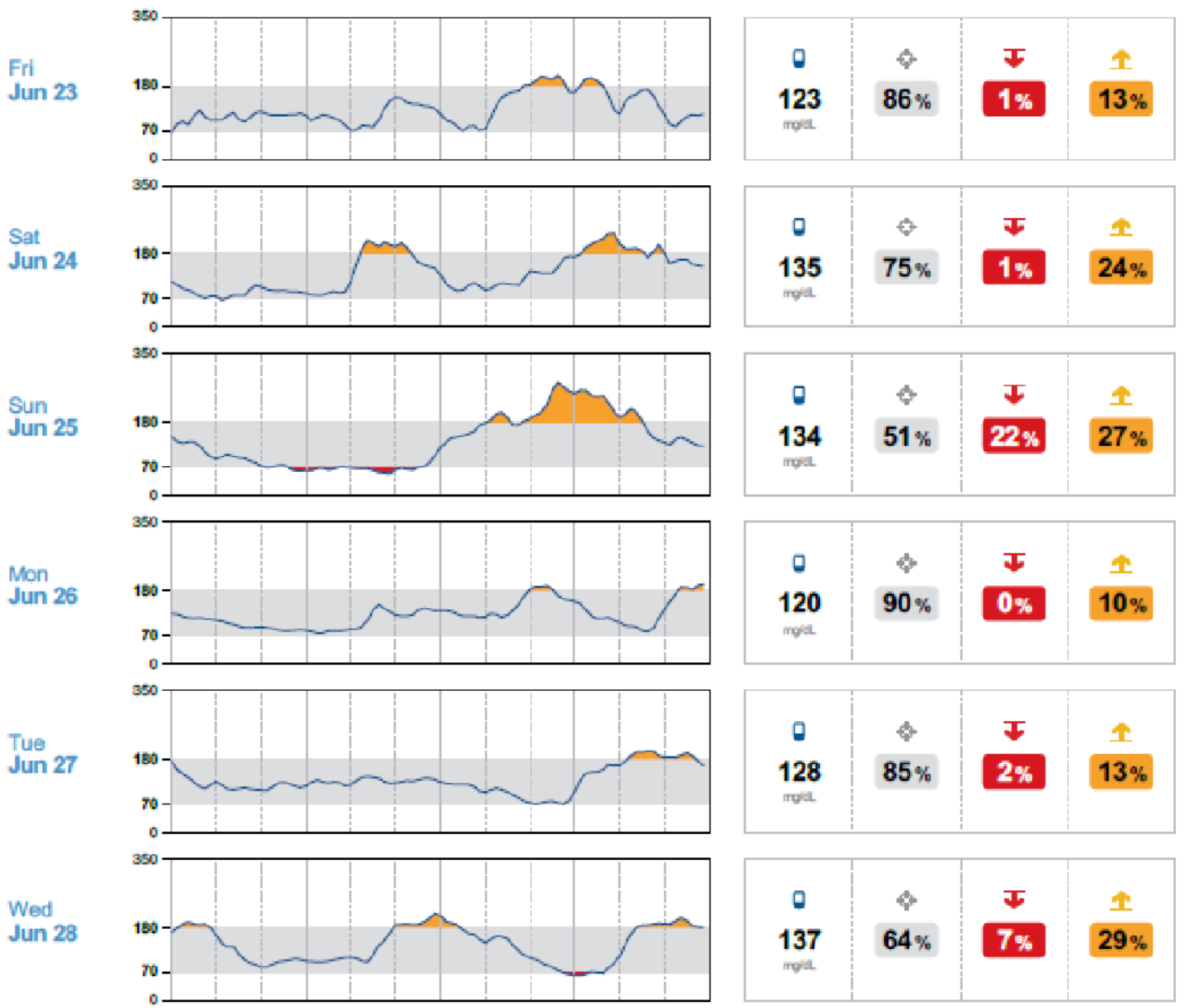
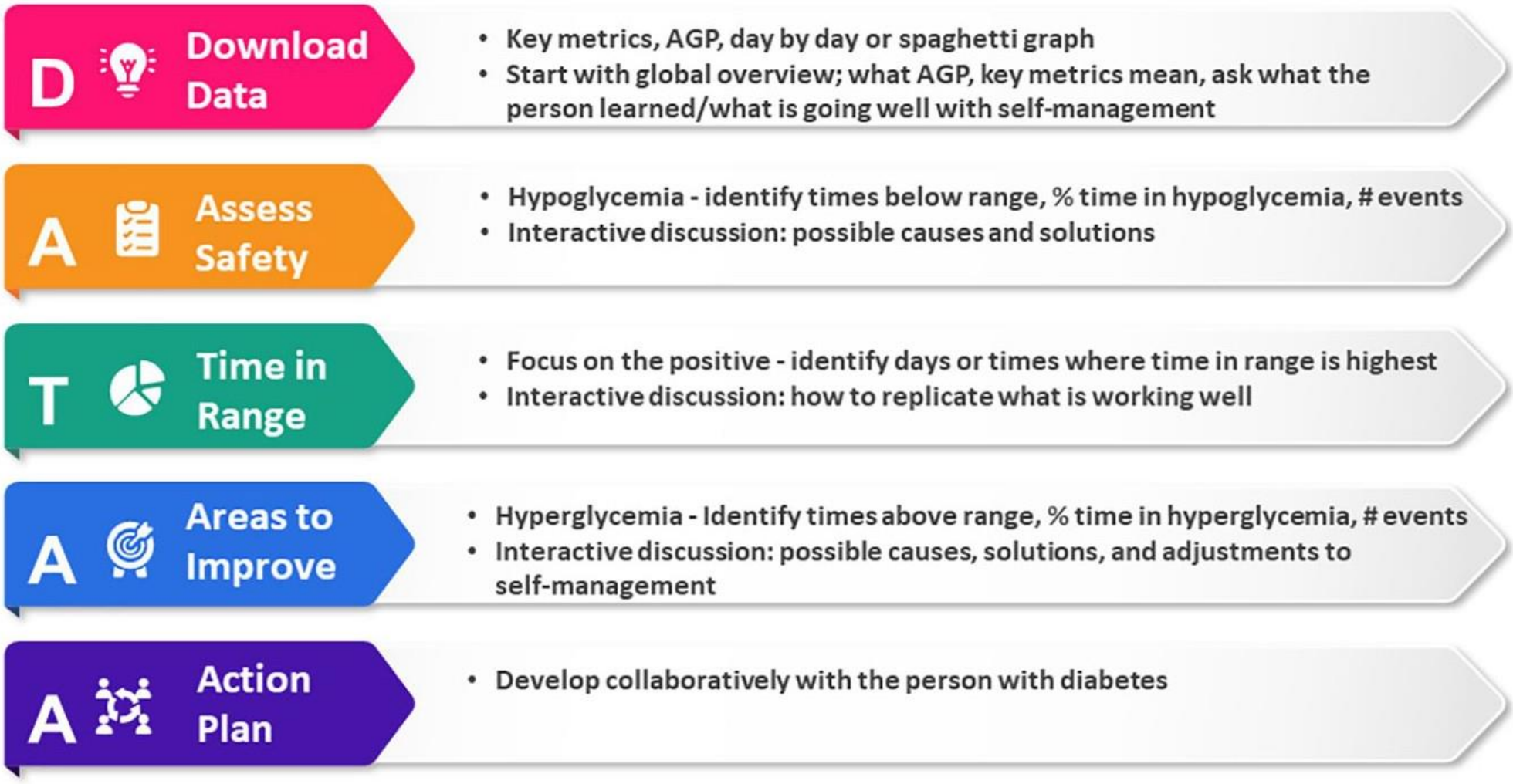


Image obtained from LibreView report.

Review of CGM - DATAA

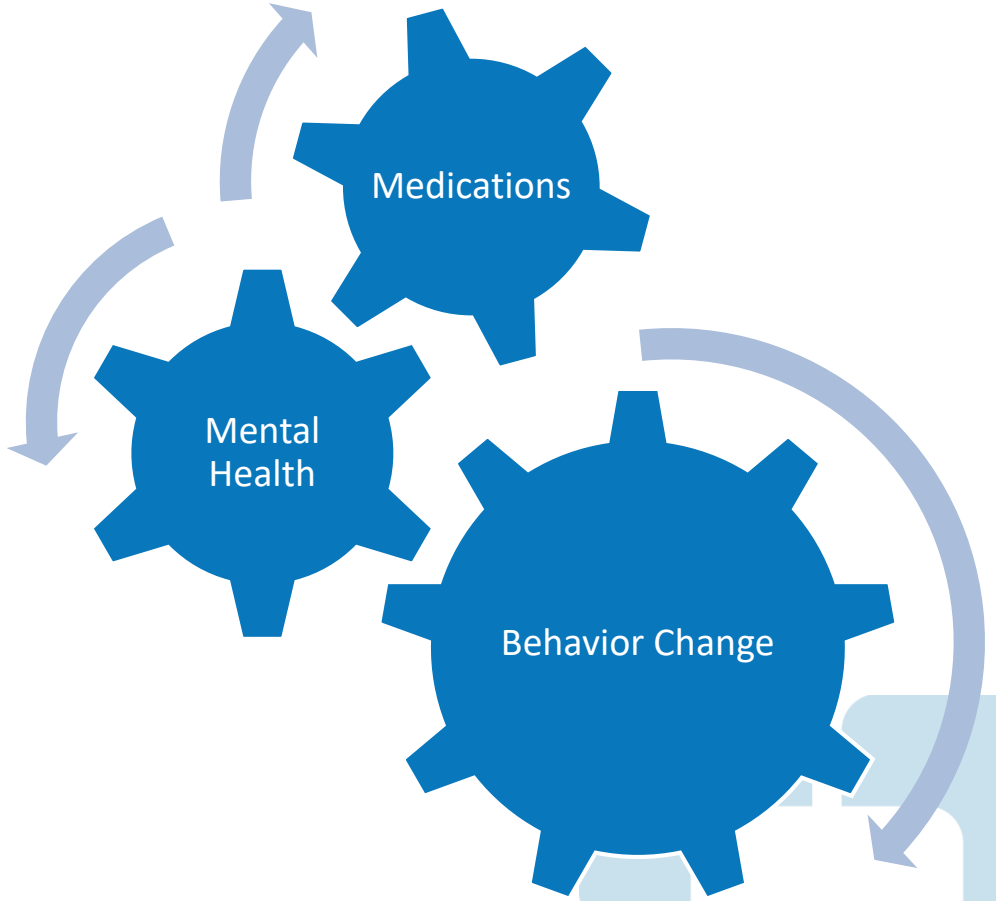


At each step, express that this is information, not good or bad

Isaacs D, Cox C, Schwab K, et al. Technology Integration: The Role of the Diabetes Care and Education Specialist in Practice. The Diabetes Educator. 2020;46(4):323-334. doi:10.1177/0145721720935123

Tips for DATA Interpretation

- Start by asking the person what they've experienced and noticed with their glucose patterns
- Avoid judgment
- Learn from 1 time episodes, but make changes based on patterns
- Fix lows first but some amount is expected (<1-4%) and if you remove all lows, you may end up with too many highs
- If it's not making sense, dig deeper (ex. missed doses, rationing, injection technique, food insecurity, etc)

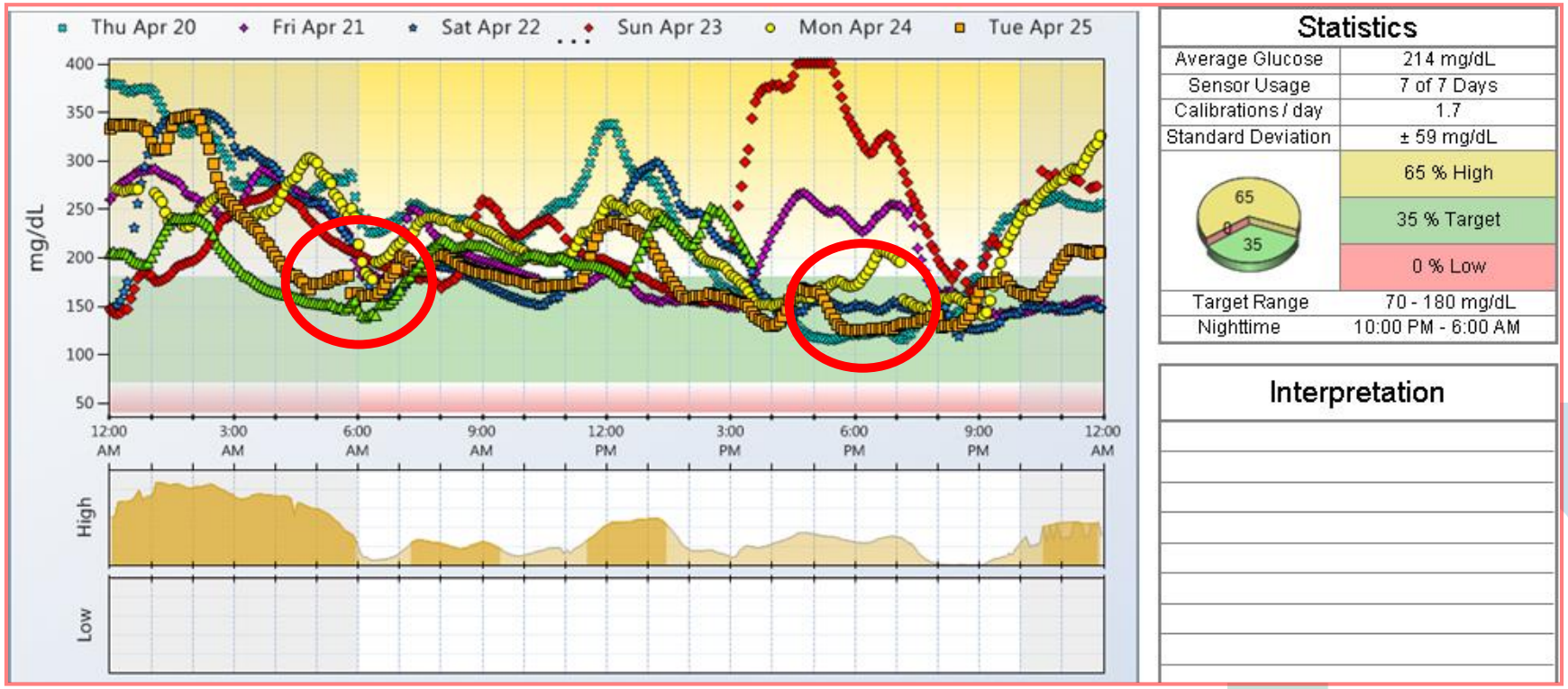


Case Studies

Meet Derek

- 48-year-old man, type 2 diabetes x 10 years, maxed out on metformin, GLP-1 agonist, SGLT2 inhibitor, sulfonylurea
- A1C = 9%-9.5% for 12 months, FBG and pre-dinner BG ≈150 mg/dL
- He agreed to wear a professional CGM for 7 days

Derek was shocked by what happened between breakfast and dinner; he agreed to start insulin.



Case

Terrance is a 60-year-old man with T2D x 12 years

Current DM2 meds:

- Metformin 1000 mg twice daily
- Glimepiride 8mg daily

Other conditions

- CKD
- Hyperlipidemia
- Hypertension

Checks BGM once daily

Pertinent Labs

- SCr = 1.38 mg/dL, eGFR = 55
- A1C = 8.2%, BMI = 34 kg/m^2

- Works in project management
- Eats 3 meals/day, snacks at night, no regular exercise
- Glucose log

Day	FBG, mg/dL
1	125
2	123
3	110
4	108
5	99
6	81
7	134

Starts CGM

D Download Data

A Assess Safety

- Which CGM key metrics are at goal?
- Which are not?
- Overall patterns?

GLUCOSE STATISTICS AND TARGETS

February 26, 2021 - March 25, 2021	**28 Days**
% Time CGM is Active	**98%**

Ranges And Targets For	Type 1 or Type 2 Diabetes
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.

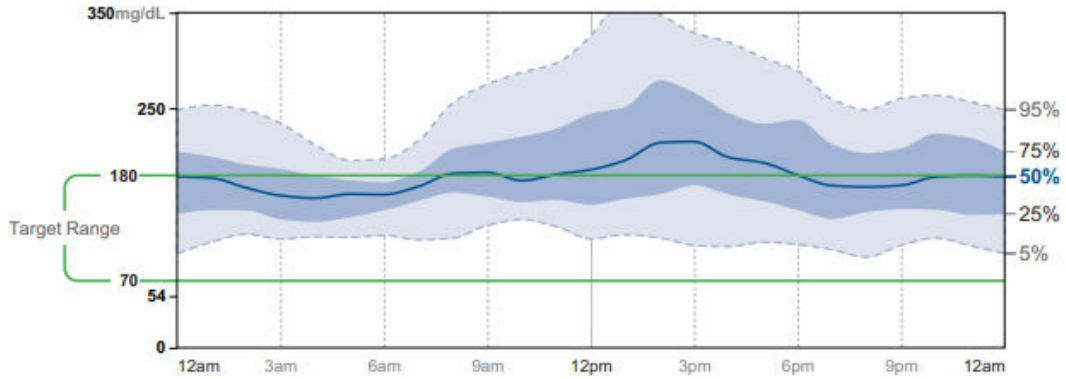
Average Glucose	**185** mg/dL
Glucose Management Indicator (GMI)	**7.7%**
Glucose Variability	**29.7%**

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

TIME IN RANGES

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.



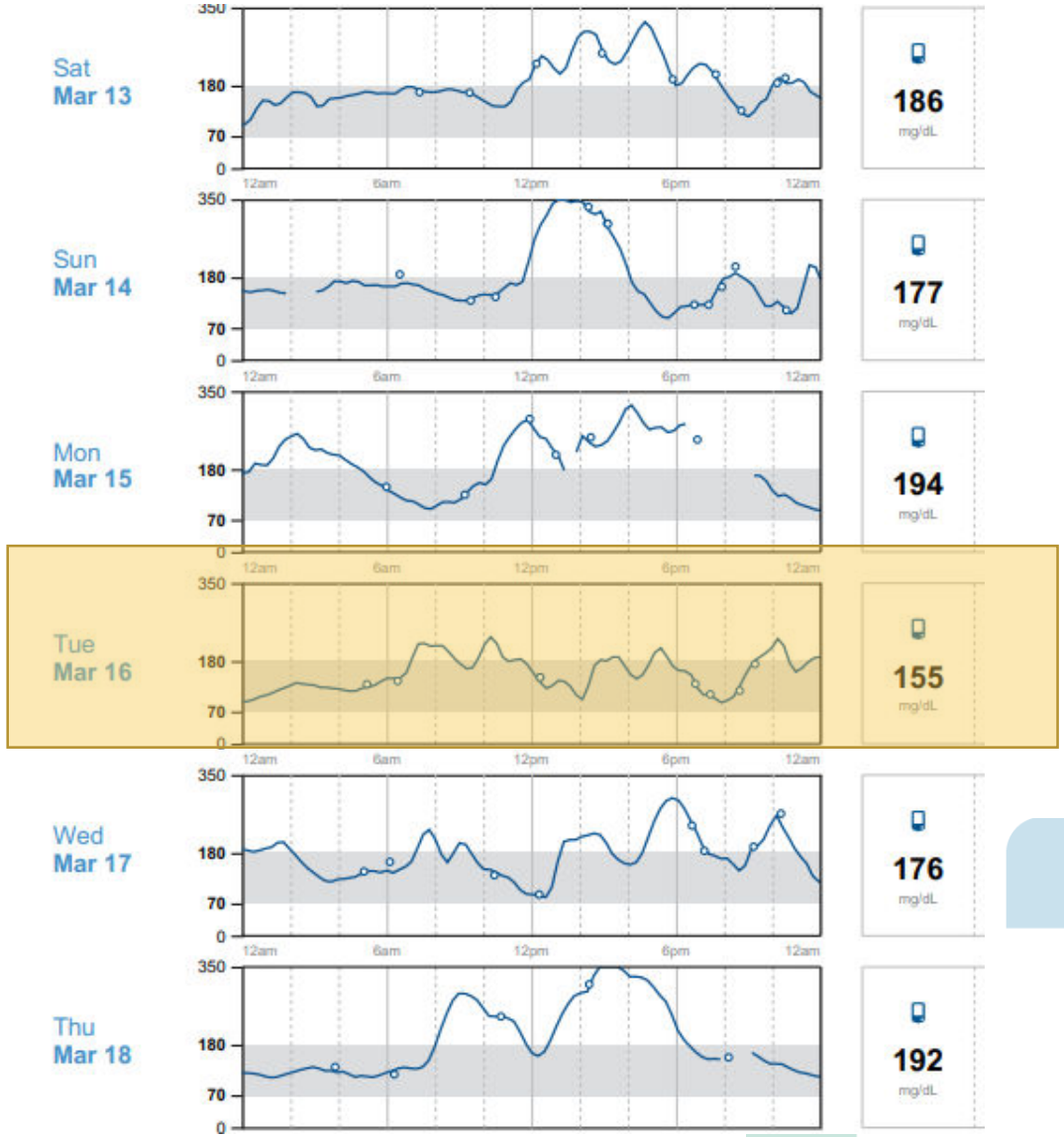
Assessment Question

Which CGM key metrics are at goal?

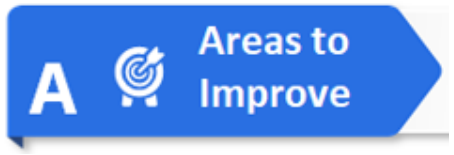
A. Time in range
B. Time above range
C. Time below range
D. Glucose management indicator

Time in Range

- Focus on the positive: what's worked well on Tue 3/16?
- Time in range is high this day
- Ate a granola bar for breakfast, grilled chicken salad at lunch, steak, greens, potato at dinner
- No missed medication doses
- Good night's sleep, low stress



Areas for Improvement



- Sun 3/14 glucose went high 12 pm
- Reports eating rice bowl and coke
- Silver lining
  - Walked around 3 pm (helped to lower glucose)
  - Avoided afternoon snacking
  - Ate low-carb dinner (salmon, salad, small potato)
  - Denies missed doses

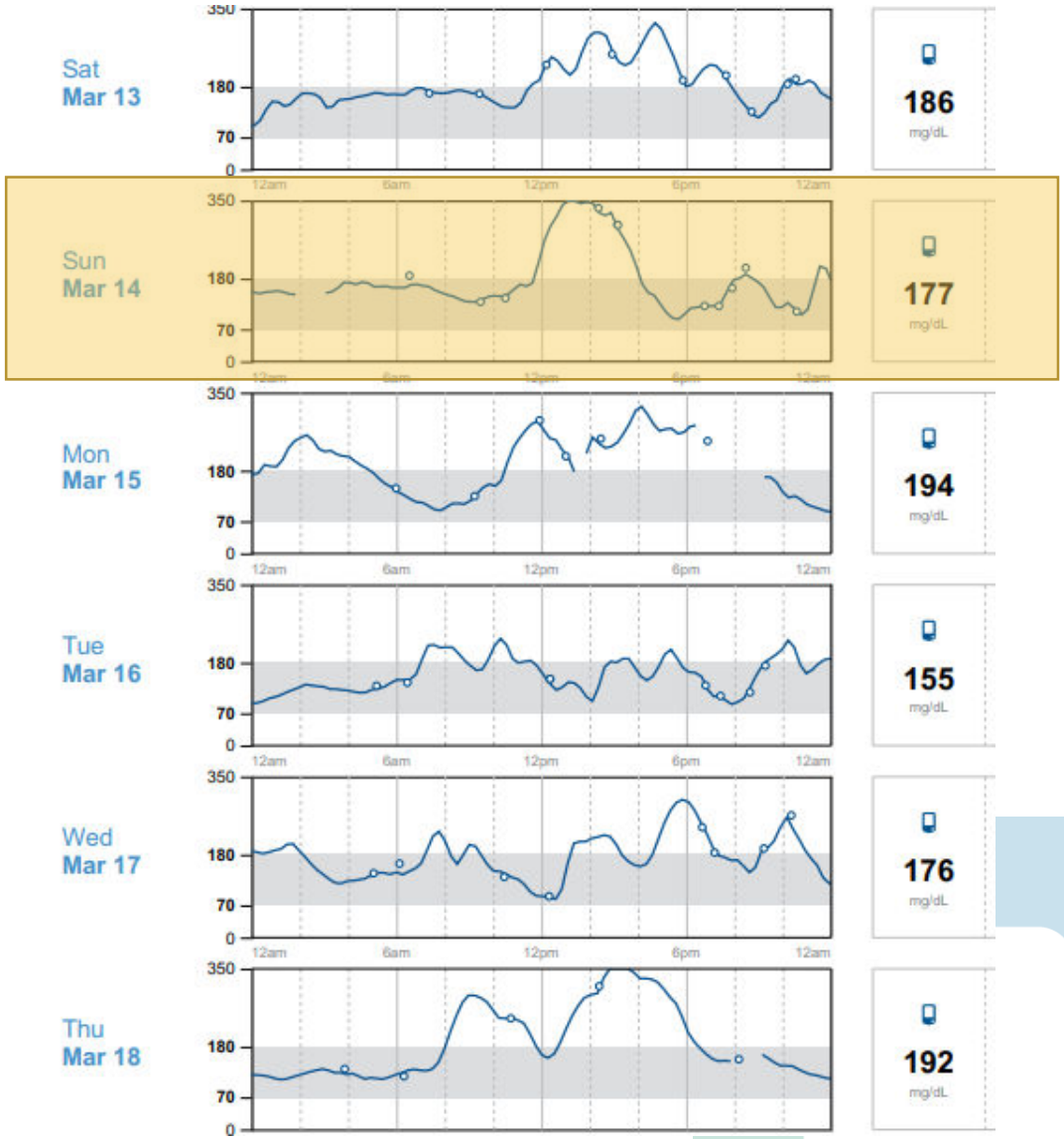
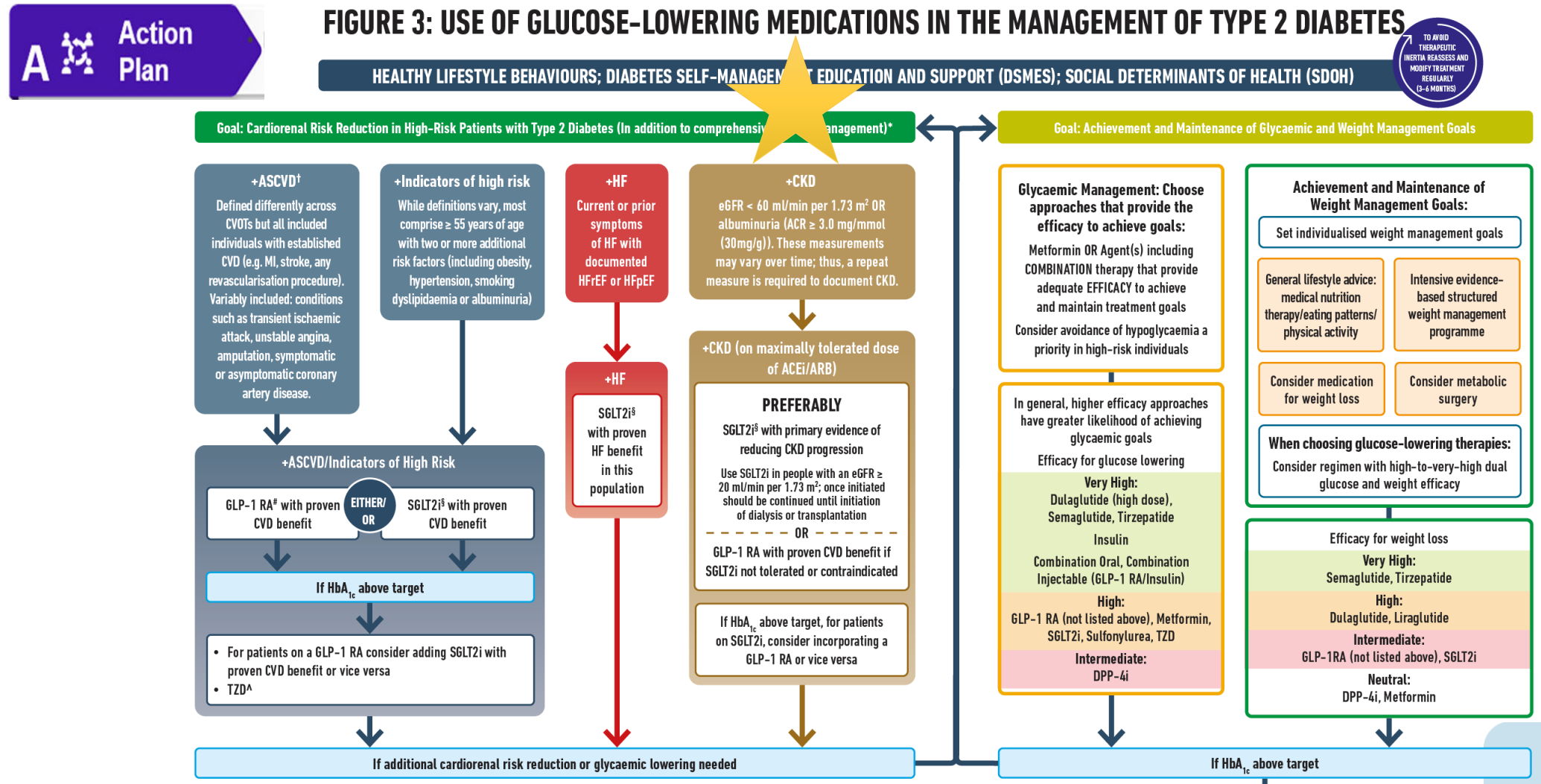


FIGURE 3: USE OF GLUCOSE-LOWERING MEDICATIONS IN THE MANAGEMENT OF TYPE 2 DIABETES



ACEi, Angiotensin-Converting Enzyme Inhibitor; ACR, Albumin/Creatinine Ratio; ARB, Angiotensin Receptor Blocker; ASCVD, Atherosclerotic Cardiovascular Disease; CGM, Continuous Glucose Monitoring; CKD, Chronic Kidney Disease; CV, Cardiovascular; CVD, Cardiovascular Disease; CVOT, Cardiovascular Outcomes Trial; DPP-4i, Dipeptidyl Peptidase-4 Inhibitor; eGFR, Estimated Glomerular Filtration Rate; GLP-1 RA, Glucagon-Like Peptide-1 Receptor Agonist; HF, Heart Failure; HFpEF, Heart Failure with preserved Ejection Fraction; HFrEF, Heart Failure with reduced Ejection Fraction; HHF, Hospitalisation for Heart Failure; MACE, Major Adverse Cardiovascular Events; MI, Myocardial Infarction; SDOH, Social Determinants of Health; SGLT2i, Sodium-Glucose Cotransporter-2 Inhibitor; T2D, Type 2 Diabetes; TZD, Thiazolidinedione.

* In people with HF, CKD, established CVD or multiple risk factors for CVD, the decision to use a GLP-1 RA or SGLT2i with proven benefit should be independent of background use of metformin;† A strong recommendation is warranted for people with CVD and a weaker recommendation for those with indicators of high CV risk. Moreover, a higher absolute risk reduction and thus lower numbers needed to treat are seen at higher levels of baseline risk and should be factored into the shared decision-making process. See text for details; ^ Low-dose TZD may be better tolerated and similarly effective; § For SGLT2i, CV/renal outcomes trials demonstrate their efficacy in reducing the risk of composite MACE, CV death, all-cause mortality, MI, HHF and renal outcomes in individuals with T2D with established/high risk of CVD; # For GLP-1 RA, CVOTs demonstrate their efficacy in reducing composite MACE, CV death, all-cause mortality, MI, stroke and renal endpoints in individuals with T2D with established/high risk of CVD.

Davies MJ, Aroda VR, Collins BS, Gabbay RA, Green J, Maruthur NM, Rosas SE, Del Prato S, Mathieu C, Mingrone G, Rossing P, Tankova T, Tsapas A, Buse JB

Diabetes Care 2022; https://doi.org/10.2337/dci22-0034. *Diabetologia* 2022; https://doi.org/10.1007/s00125-022-05787-2.

Assessment Question

3. **What is the most appropriate medication adjustment for Terrance?**

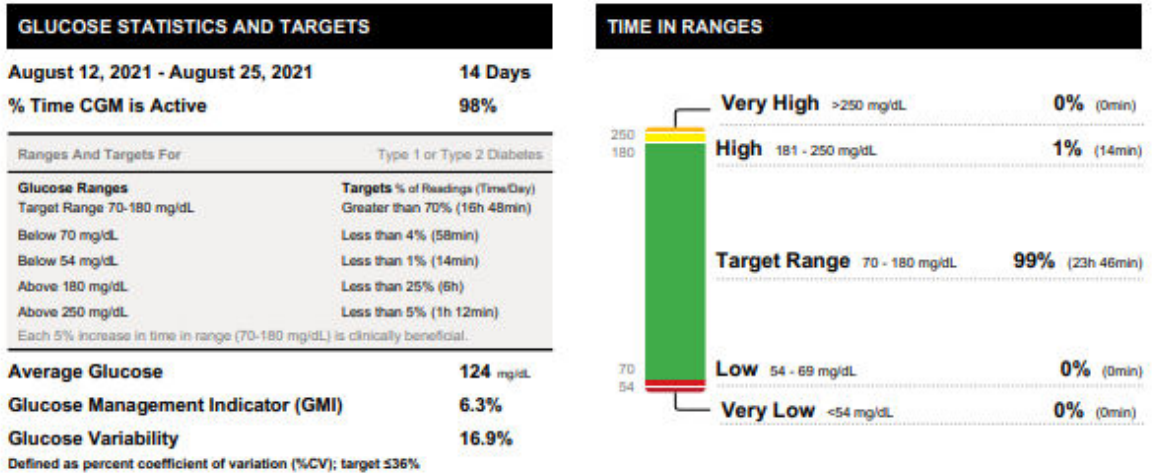
A. Add DPP4 inhibitor
B. Add GLP-1 receptor agonist
C. Add SGLT2 inhibitor
D. Lifestyle modifications only

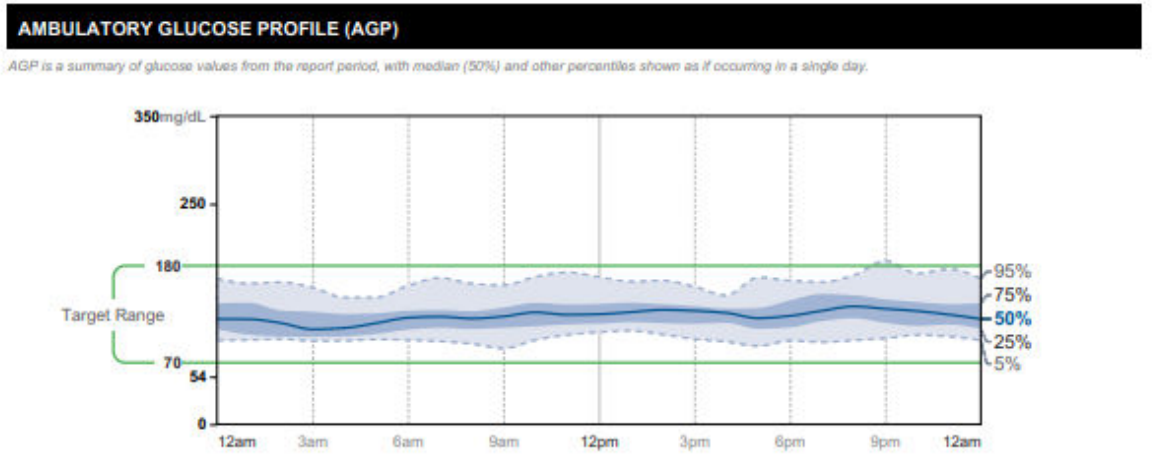
Action Plan

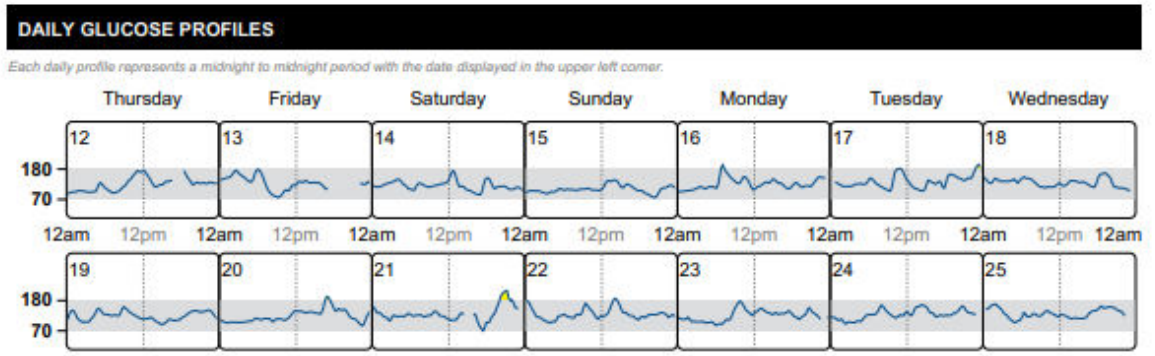
- In collaboration with Terrance
  - Lifestyle changes
    - Incorporate a brisk walk 3 days per week
    - Reduce high-carbohydrate foods like fries
  - CGM optimization
    - Alerts, high for 280
  - Medication adjustments
    - Add a medication to help his CKD + optimize glucose → SGLT2 inhibitor
  - Follow-up in 3-4 weeks

3 Months Later

DM2 Meds:
Empagliflozin 10mg qday
Metformin 1000mg BID







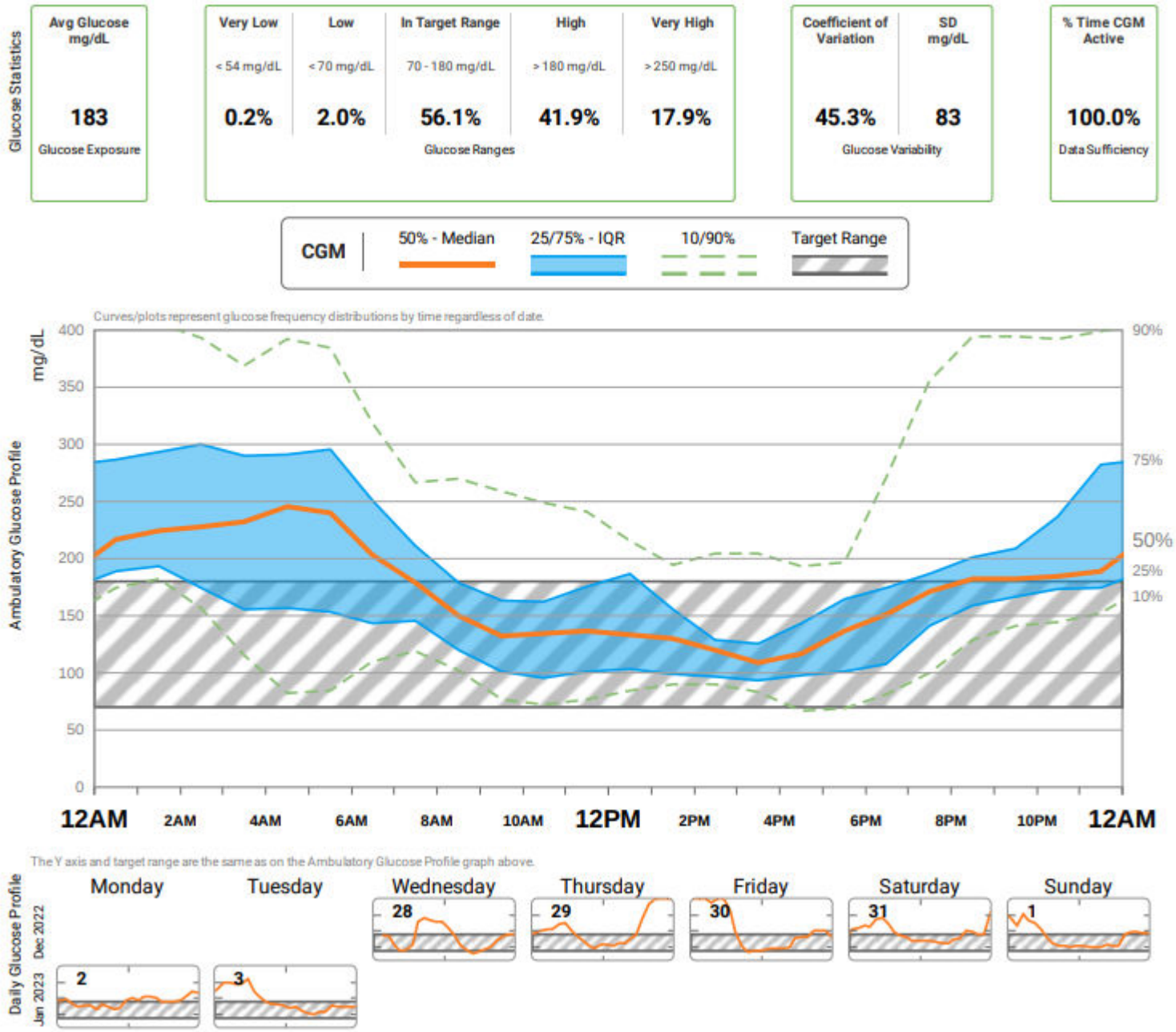
Patient Case

75 yo F with 25 year h/o T2DM. PMH includes HTN, hyperlipidemia, hypothyroid, obesity, ASCVD.

Current DM Meds

-Insulin glargine inject 50 units QAM and 40 at night
-Insulin aspart 8-10-10 units plus correction scale
-Metformin 1000 mg daily
-Semaglutide, 0.25mg weekly (2 doses so far)

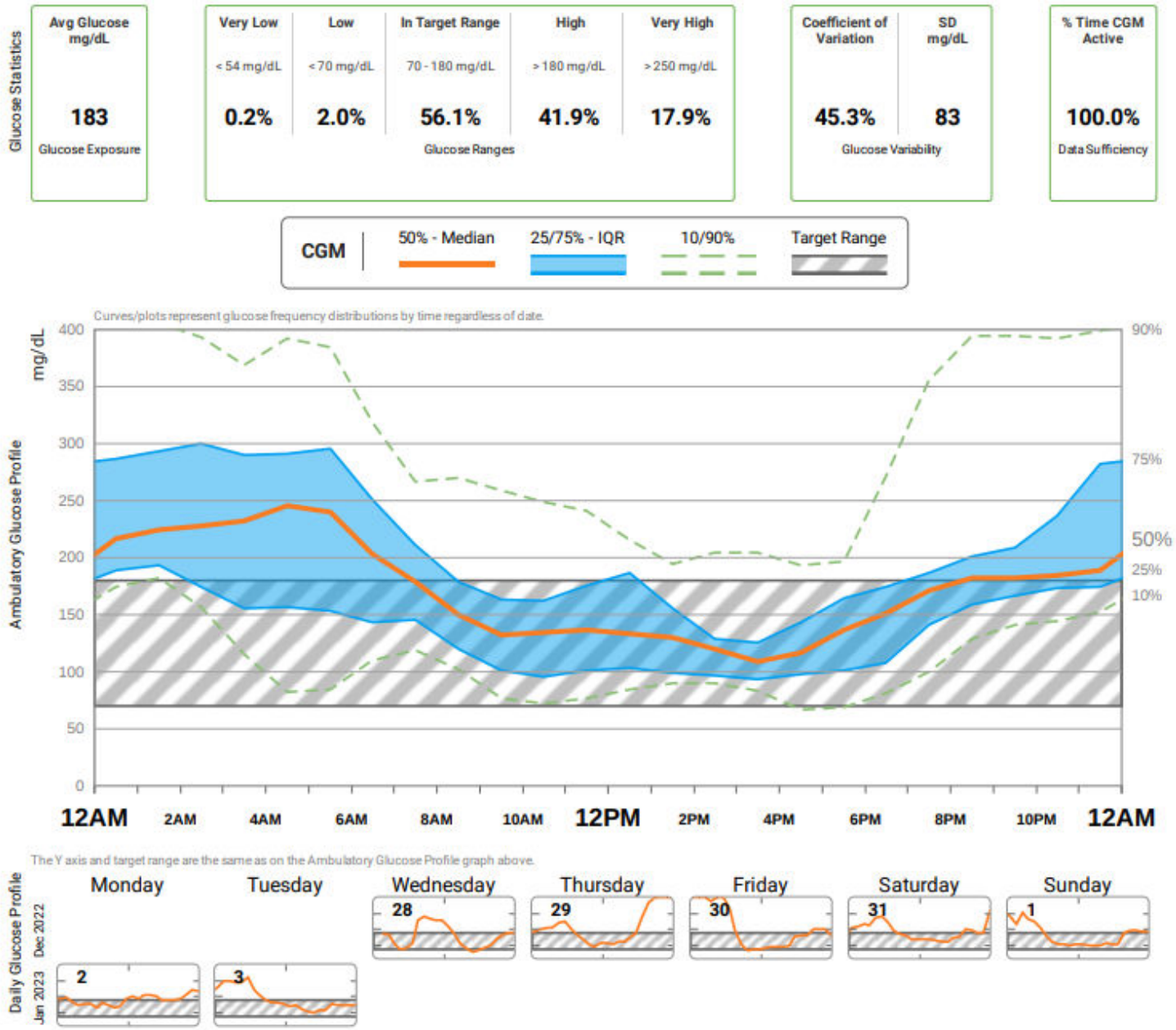
Wears rtCGM



Clarity report obtained from Diana Isaacs

Which of the following CGM key metrics is at target?

A. Time in range
B. Time above range
C. Coefficient of variation
D. Time below range



Clarity report obtained from Diana Isaacs

Using DATAA

A Assess Safety

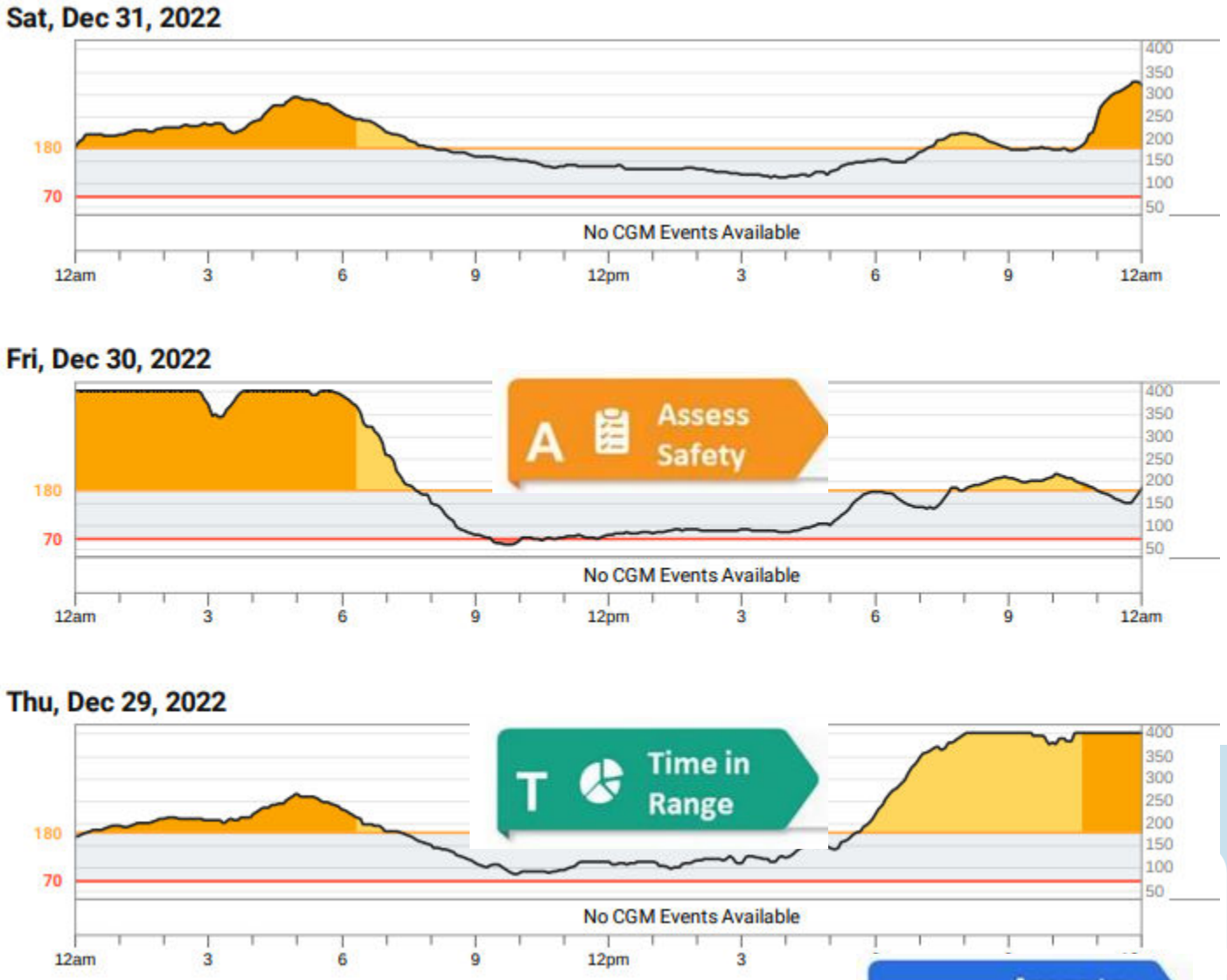
Less of an appetite since taking semaglutide, often going low during the day

T Time in Range

During the day, glucose often steady, but also having to drink juice to keep from going low

A Areas to Improve

Skipping aspart doses because running low, leading to rebound highs



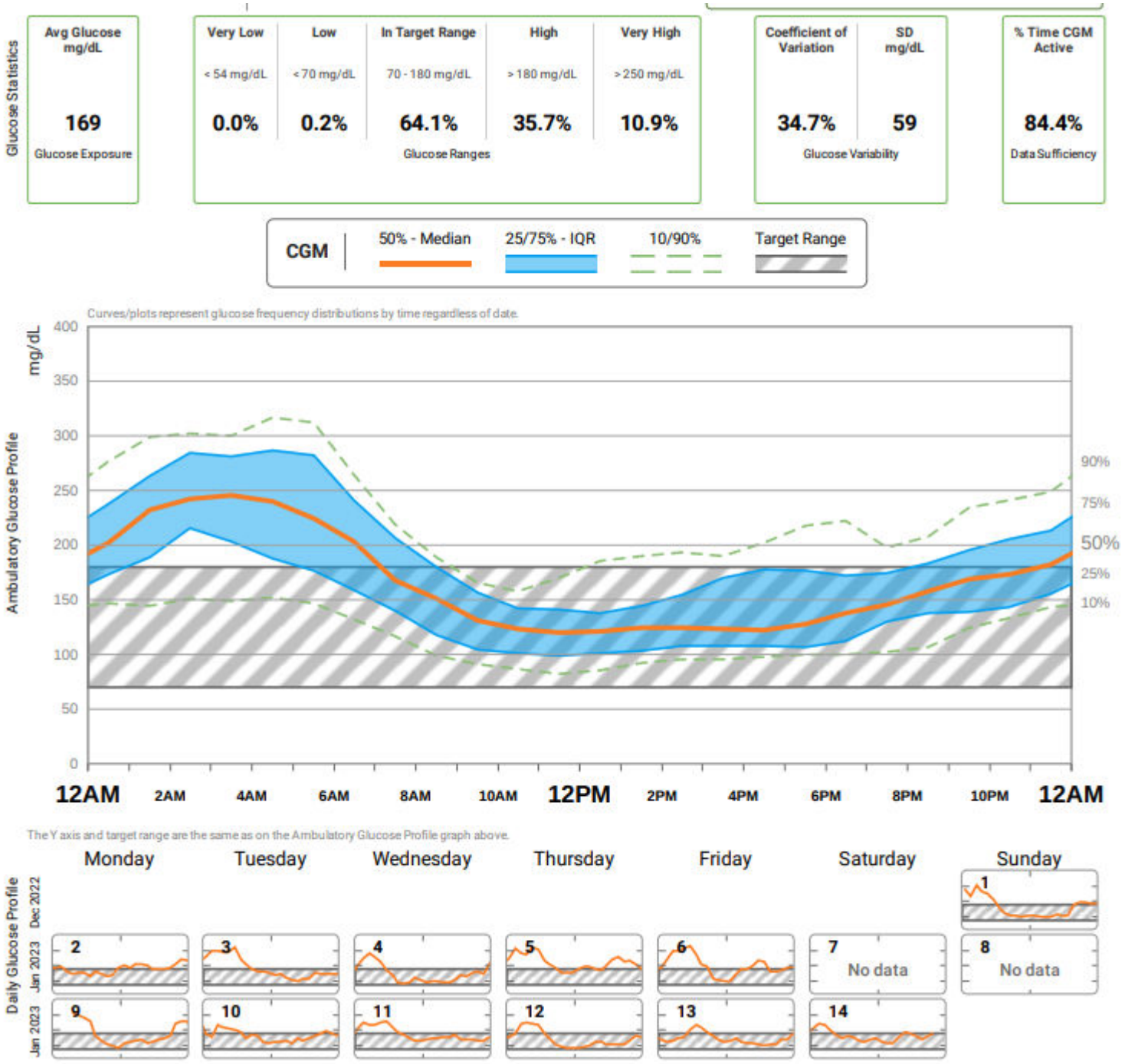
Clarity report obtained from Diana Isaacs

Action Plan

- Continue semaglutide 0.25mg weekly x 2 more weeks, then titrate up to 0.5mg weekly
- Decrease insulin glargine to 45 units qam and 35 units qpm
- Continue insulin aspart 8-10-10 + correction scale
- Continue metformin 1000mg daily

1 month later

- Average glucose improved
- Time in range increased
- Glucose variability improved
- Less hypoglycemia



Clarity report obtained from Diana Isaacs

Insulin Pumps

First Pumps: 1963

Common Insulin Pump Features

- Bolus calculator
- Temporary basal or temporary target
- Insulin-on-board/active insulin feature
- Multiple basal patterns
- Small dose increments
- Integration with CGM
- Designed to work with U100 insulin
- Most have a 4-5 year warranty/contract

Ideal Pump Candidates

- Motivated
- Checking BG 4+ times/day or wearing CGM
- Carbohydrate counting or good with estimates
- Ability to learn pump programming
- Willing to follow up regularly with health care team
- Can afford the pump/supplies
- Following hyperglycemia treatment instructions

Hybrid-Close Loop (HCL)

- Automates insulin delivery based on CGM readings
- All systems auto-adjust basal rates
- Some systems give auto-corrections
- All systems require the user to bolus for carbohydrates
- Requires user to use CGM and maximize time spent in HCL to get most benefits

“Smart” Insulin Pumps

Omnipod DASH
(Insulet)

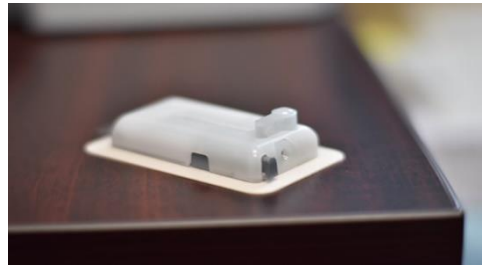
Omnipod 5
(Insulet/Dexcom)

T:slim X2 with G6 CGM
(Tandem/Dexcom)
Basal IQ
Control IQ

770G with Guardian 3
(Medtronic)

780G with Guaridan 4

Patch Pumps



Cequr Simplicity

- Bolus pump patch only
- Approved for adults with T1DM or T2DM
- Holds up to 200 units of rapid acting insulin
- On-demand bolus doses in 2 unit increments
- Doses administered via clicks directly on the device
- Must be changed every 3 days

V-Go

- 24 hr. basal/bolus patch pump
- Approved for adults with T2DM
- Allows 20, 30, 40 unit basal rate options
- On-demand bolus doses in 2 unit increments
  - Up to 36 units/24 hrs
- Doses administered via clicks directly on the device
- Must be changed daily

https://myceqursimplicity.com/
https://www.go-vgo.com/

Omnipod DASH

- No tubing
- Pod (pump) includes infusion set
- All programming done via PDM
  - Locked Android smartphone
  - Bluetooth connection
- Rechargeable battery
- Food database
- Holds 200 units
- 0.05 unit basal increment
- Automatic cannula insertion and priming
- Dash blue tooth connected with contour meter

Omnipod 5

- HCL system
- Minimum age, 2 years, 10 units of insulin
- Glucose targets from 110-150mg/dL adjustable by time or day
- Adaptive basal rates
- HypoProtect for times to reduce risk of lows
  - Reduce insulin to target of BG 150
- SmartBolus calculator informed by Dexcom G6 CGM value and trend
- Control system from a compatible personal smartphone
- Adjustable settings: carb ratio, sensitivity, active insulin time, recommended bolus dose
- Plans to integrate with Libre in the future

Device Comparison — Panther Program (bdcpantherdiabetes.org)

Medtronic 770G

- 770G with SmartGuard™ Auto Mode
  - Adjusts basal insulin every 5 min based on CGM readings to target glucose of 120 mg/dL
  - Bluetooth connectivity
  - 780G software upgrade when approved
- Minimum age: 2 years, 8 units insulin
- Suspend before/on low options (in manual mode)
- Temp target of 150 available
- 300 unit reservoir
- Connected Accu-check Guide meter and Guardian 3 CGM
- Mobile app for data sharing/viewing
- 300-unit reservoir
- 0.025 unit basal increment

https://www.medtronic.com/us-en/healthcare-professionals/products/diabetes/insulin-pump-systems.html

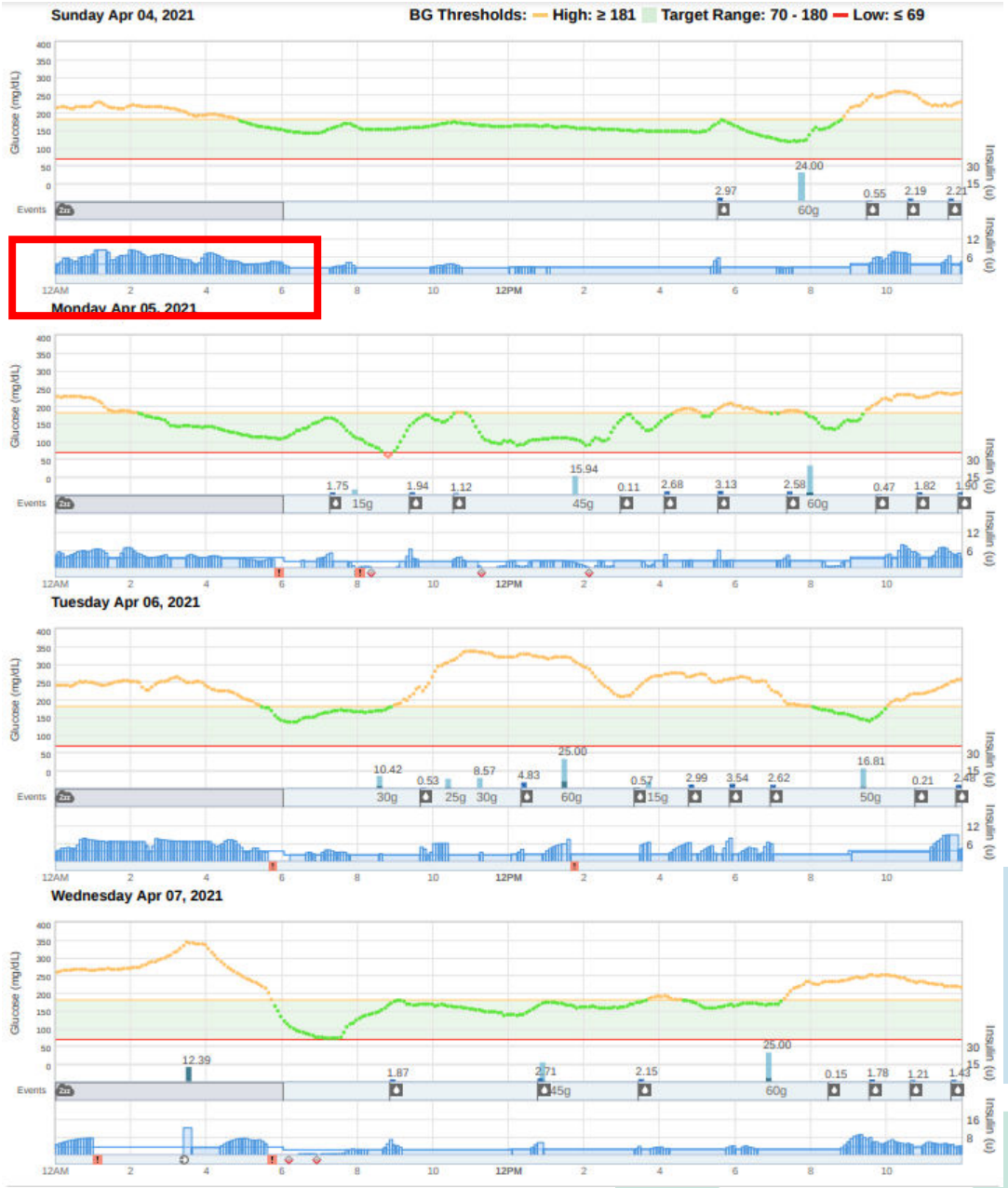
Medtronic 780G

- Basal rate automation
- Automatic correction boluses
- Adjustable target to 100mg/dL
- Increased time in closed loop
- Bluetooth connectivity, remote software upgrades
- Mobile app for secondary data display and wireless data uploads
- Guardian Sensor 4 non-adjunctive (no calibrations)
- Future:
  - Synergy sensor: disposable, 50% smaller

Control IQ

		Control-IQ	Sleep Activity	Exercise Activity
Delivers	Delivers an automatic correction bolus if sensor glucose is predicted to be above ___ mg/dL	180	--	180
Increases	Increases basal insulin delivery if sensor glucose is predicted to be above ___ mg/dL	160	120	160
Maintains	Maintains active Personal Profile settings when sensor glucose is between ___ - ___ mg/dL	112.5 - 160	112.5 - 120	140 - 160
Decreases	Decreases basal insulin delivery if sensor glucose is predicted to be below ___ mg/dL	112.5	112.5	140
Stops	Stops basal insulin delivery if sensor glucose is predicted to be below ___ mg/dL	70	70	80

Automatic correction dose of 60% value hour if 30 min predicted glucose >180mg/dL



Tandem t:slim X2

- Touch screen
- Rechargeable
- 300-unit reservoir

  0.001 unit basal increment

  Integrated Dexcom G6 CGM

  Software updates available
- 2 algorithms:
  - Basal IQ – basal adjusts and suspends for lows
  - Control IQ – basal adjusts for lows and highs; automatic hourly correction boluses for highs

Tandem T:Slim X2 with Basal IQ

- Touch screen
- Lithium rechargeable battery
- 300-unit reservoir
- Indicated ages ≥ 6 years
- 0.001 unit basal increment
- Integration with Dexcom G6
- Basal IQ- suspends basal if CGM predicted to decrease to < 80 mg/dl within 30 minutes

BASAL IQ Example

Tandem T:Slim X2 with Control-IQ

- Advanced hybrid-closed loop system
- Algorithm adjusts insulin delivery from programed “manual” settings
- Automatic correction doses
  - Up to 1 every hour
  - Calculated at 60% of programmed correction factor
    (target of 110)
- User must still bolus for carbs (and additional correction doses)
- FDA approved 6+ years, 55lbs, 10 units insulin/day
- Phone app to bolus

Control IQ Targets

		Control-IQ	Sleep Activity	Exercise Activity
Delivers	Delivers an automatic correction bolus if sensor glucose is predicted to be above ___ mg/dL	180	--	180
Increases	Increases basal insulin delivery if sensor glucose is predicted to be above ___ mg/dL	160	120	160
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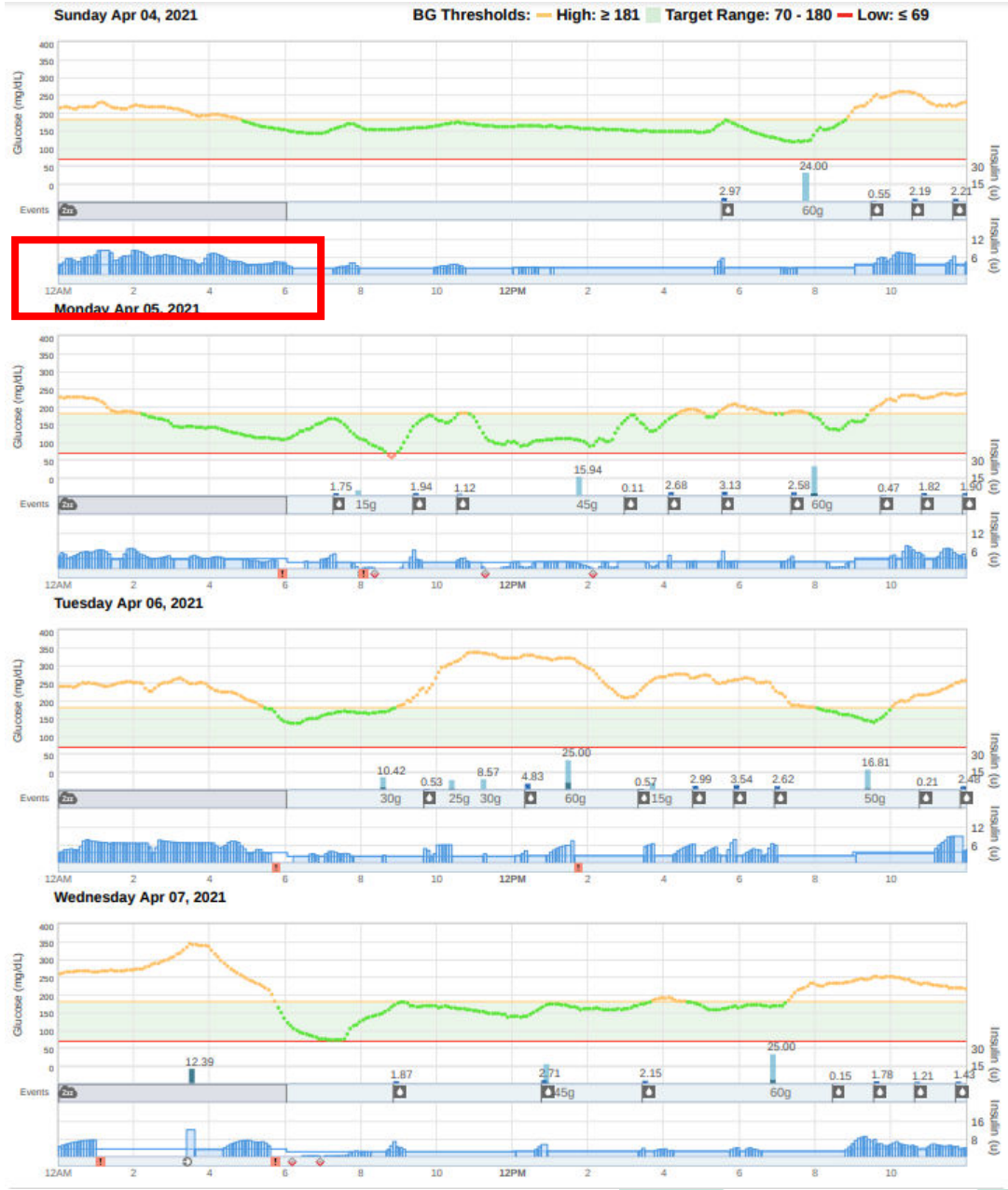


Tidepool Loop is Now FDA Approved

ACE Pump

"alternate controller-enabled pump"
What that means: the pump is designed to be able to work safely with more than one type of algorithm that adjusts insulin

iCGM

"integrated continuous glucose monitor"
What that means: the CGM system meets FDA's criteria for accuracy and safety for dosing insulin

iAGC

"interoperable automated glycemic controller"
What that means: The algorithm (computing logic) has been designed to communicate with other compatible diabetes device components in a modular system.

****Submission had over three times the clinical data of the Medtronic 670G, Control IQ, and Omnipod 5 pivotal studies combined.

How Will FDA Approved Loop Be Different?

- Prescription only. Age 6 and Up.
  - Download the app from the App Store.
  - Prescription code needed; Rx sent to pharmacy
- Correction Range 87 mg/dL-180 mg/dL.
- Insulin action is fixed with Ultra Rapid, Rapid Acting
- Commercialization plans necessary with device partners to support interoperable system are being finalized.
- First automated insulin dosing app with Apple Watch compatibility

User Interface on App

Lollipop, Taco, Pizza Bolus

Bolus

Temporary Target

Set Premeal Target

Correct High Blood Sugar

Pump Comparison

	Omnipod 5	Control IQ	770G	780G
Min age	2 years	6 years	2 years	7 years
Min daily insulin	5 units	10 units, 55lbs	8 units	8 units
Max fill	200 units	300 units	300 units	300 units
Basal increment	0.05 units	0.001 units	0.025 units	0.025 units
Bolus increment	0.05 units	0.01 units	0.025 units	0.025 units
Site change frequency	3 days	3 days	7 days (extended infusion set)	7 days (extended infusion set)
CGM compatibility	Dexcom G6	Dexcom G6	Guardian 3	Guardian 4
Calibration	No	No	3-4/day	No
CGM trend in calculator	Increase up to 30% Decrease down to 100%	No	No	No

Critical Thinking

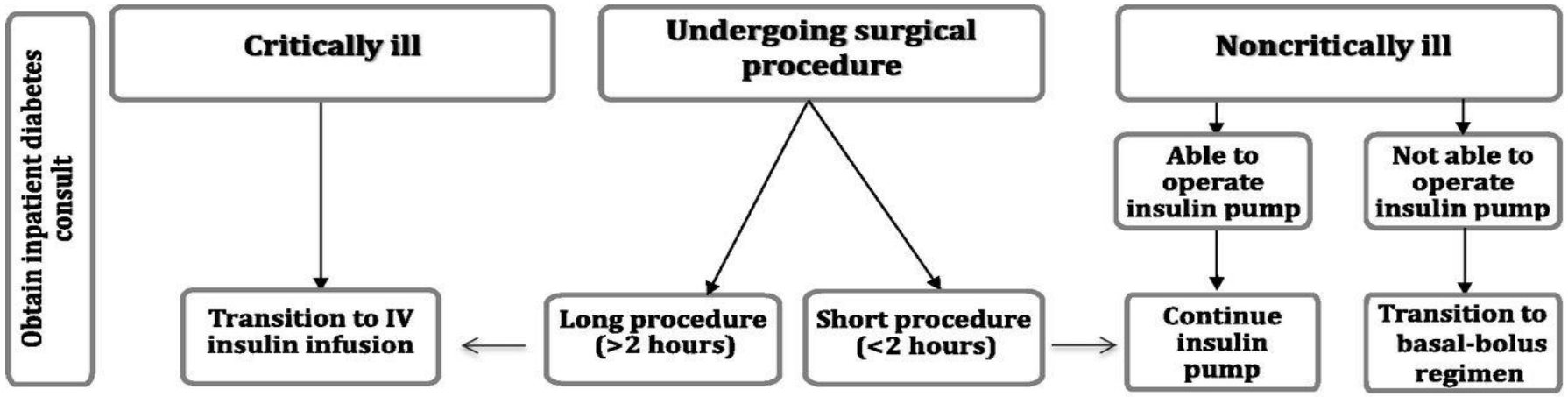
When should a provider consider discontinuing an insulin pump during hospitalization?

Technology in the Hospital

- Several inpatient studies have shown that CGM detected a greater number of hypoglycemic events than POC glucose testing
  - Overall, did not improve glucose control
- Patients who are comfortable using their diabetes devices (insulin pumps, sensor) should be given the chance to use them in an inpatient setting if they are competent to do so.
- Health care institutions must have clear policies and procedures to maximize safety and to comply with existing regulations related to self-management of medication.

Diabetes Care 2020 Jan; 43(Supplement 1): S77-S88
Umpierrez G et al. Diabetes Care 2018 Aug; 41(8): 1579-1589..

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

Umpierrez G et al. Diabetes Care 2018 Aug; 41(8): 1579-1589.

Contraindications to Insulin Pumps in the 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
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
Patient at risk for suicide

Umpierrez G et al. Diabetes Care 2018 Aug; 41(8): 1579-1589.

Connected Insulin Pens

The Insulin Delivery Landscape

Smart Insulin Pens

11.3% of US population with diabetes
7.2 million using insulin

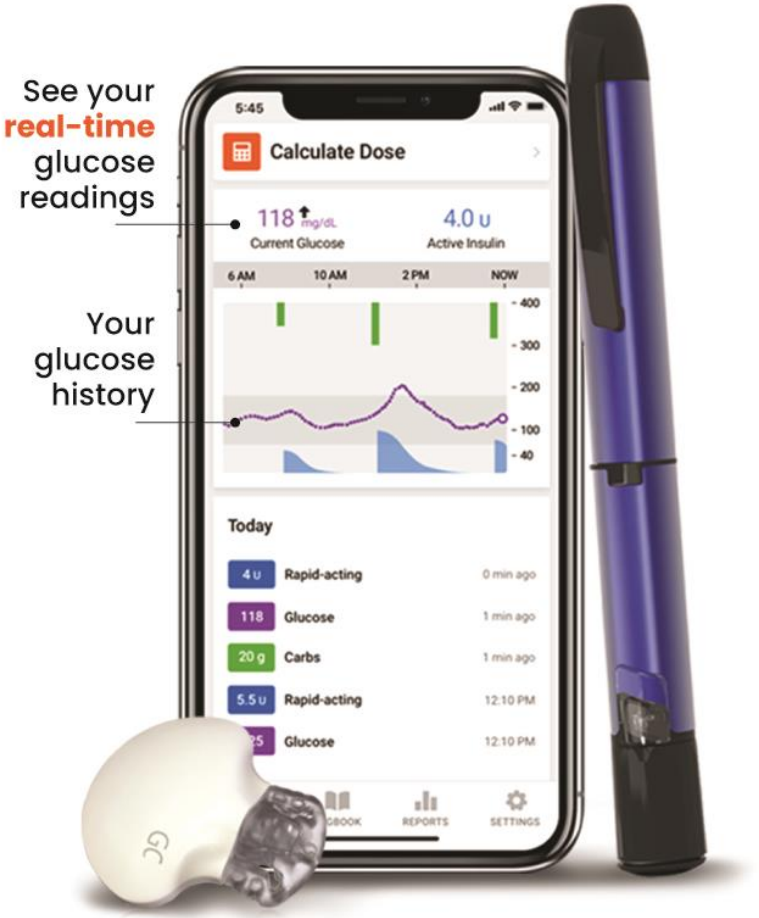
Traditional Insulin Pen,
Vial and Syringe

Smart Insulin Pumps

Basic Patch Pumps,
Inhaled Insulin

Diabetes Care 2018 Jun; 41(6): 1299-1311

Connected Pens



InPen with Guardian or Dexcom

Bigfoot Unity with Libre 2

Tempo with Dexcom

Mallya

InPen

- Delivers up to 30 units of insulin per dose
- Delivers in ½-unit increments
- Disposable needles (not included)
- 1 year life span
- Does not require charging
- Comes in blue, gray, and pink
- Integrates with Apple Health and Glooko
- Requires a prescription, uses cartridges
- Compatible with: Humalog, NovoLog, and Fiasp U100 3.0 mL prefilled cartridges
- Multiple pens can be paired to the InPen app.

https://www.companionmedical.com/InPen

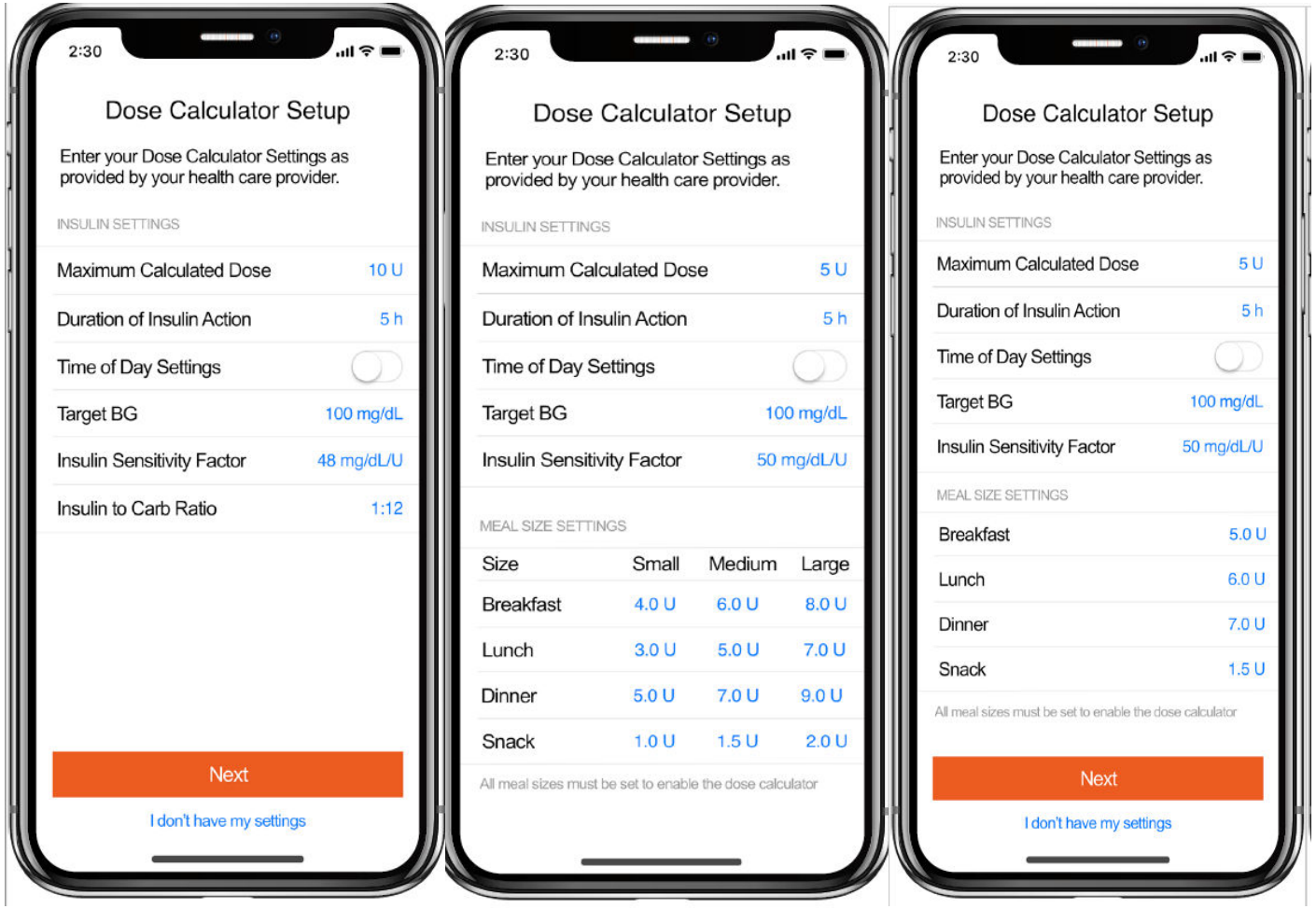
Bigfoot Unity Diabetes Management System

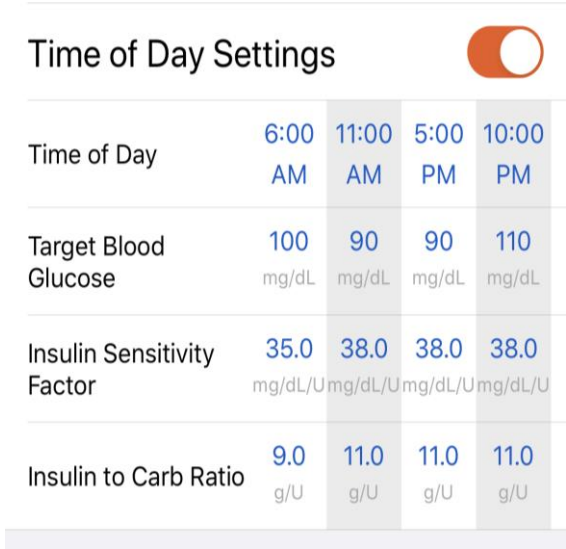
- Cleared by the FDA for ages over 12 years
- Smart insulin pen caps fits onto most commercially available insulin pens
- 2 versions of the pen cap:
  - black for basal and white for bolus
- Uses glucose data from Freestyle Libre 2 CGM
  - Scan the sensor with the pen cap
- Recommended dose displayed by pen cap
  - 3 options based on small, medium large or carb counts
- Will not recommend insulin within 3 hours of last dose
- Records when a dose was taken (pen cap off for >4 seconds)
- Pen caps are rechargeable

Lilly Tempo Smart Button

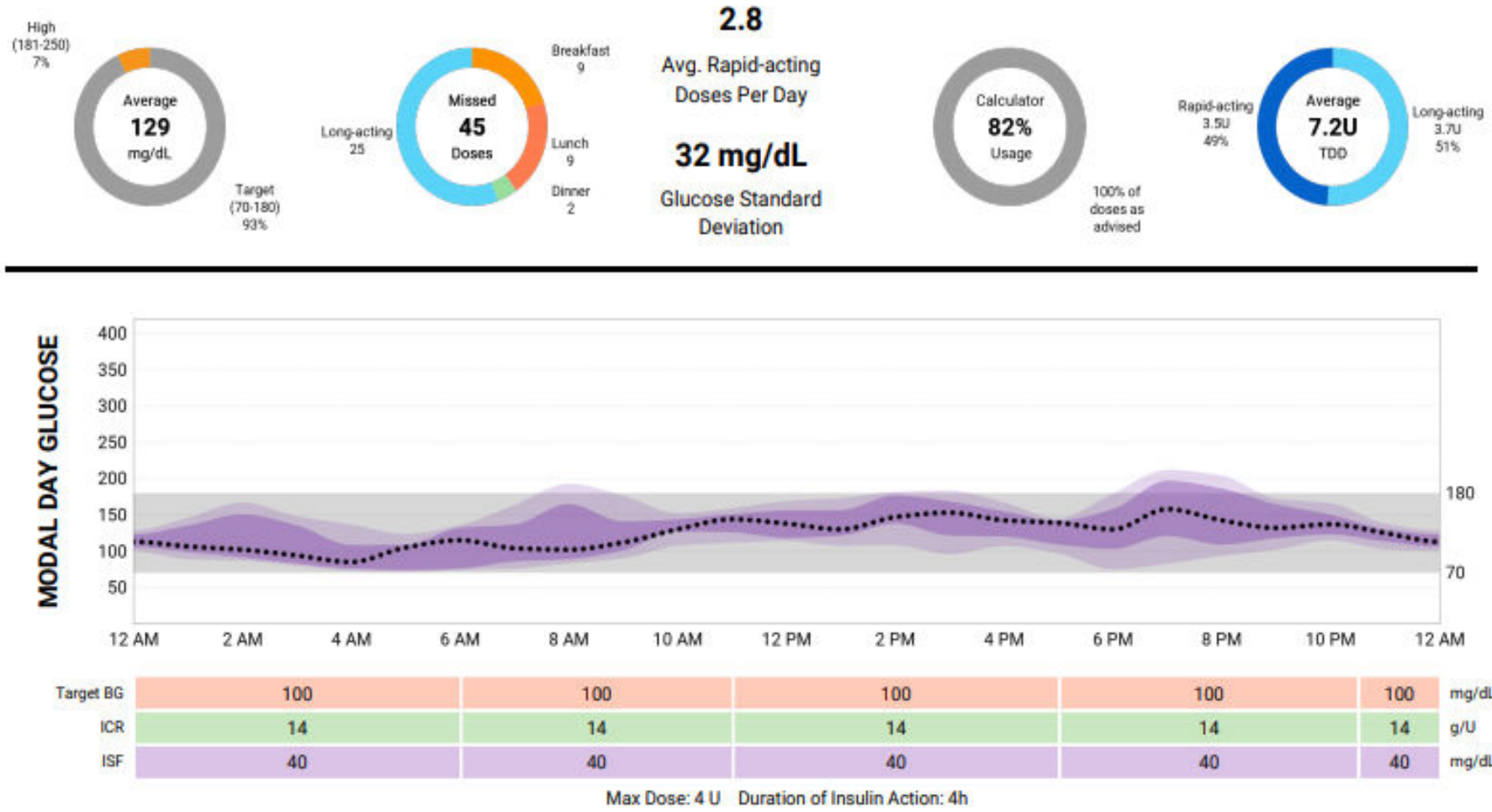
- Tempo pen available with Lyumjev, Basaglar, Humalog
- Button uses Bluetooth to transfer insulin dose to mobile app
- TempoSmart App integrates insulin dosing data with glucose, food, exercise, and sleep data
- Set personalized reminders and alerts

Therapy Settings

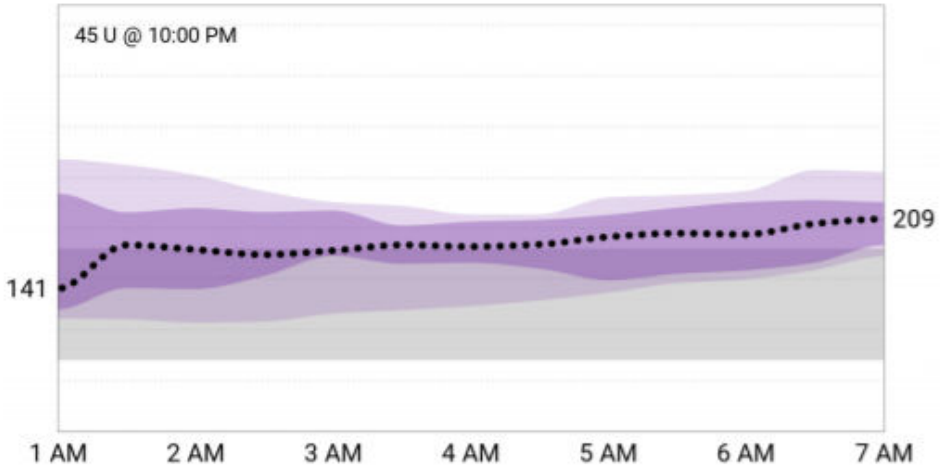




Connected Pen + CGM Data



LONG-ACTING ASSESSMENT

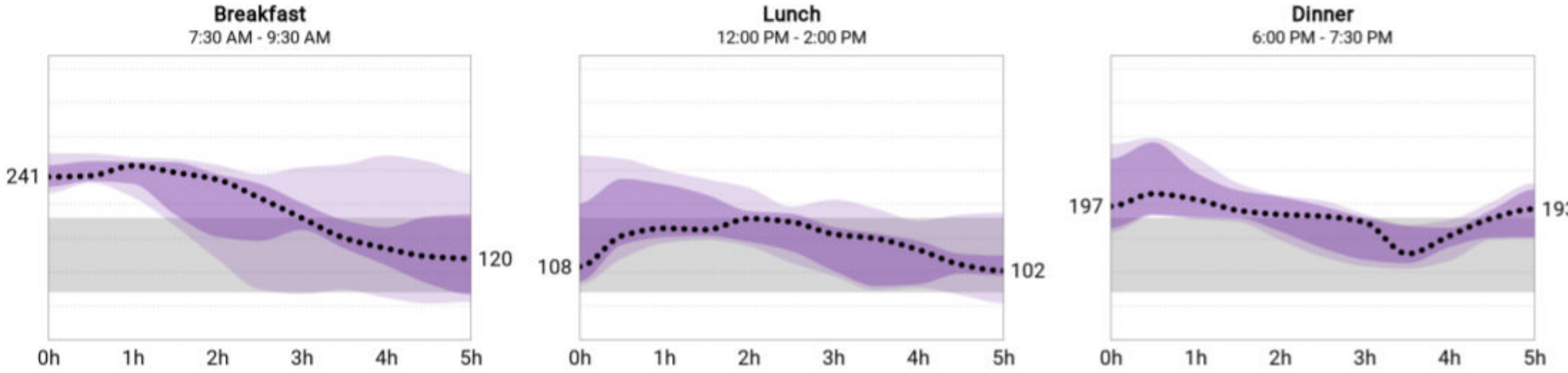


Days Included in Assessment	7 of last 14 days
Average Daily Dose Taken	45 U
# Days with Glucose < 70 mg/dL	0
Median Bedtime to Fasting (Change)	141 to 209 (+68 mg/dL) ▲

Note: Days with overnight boluses are excluded.

▲ Rising fasting glucose of 30 mg/dL or more may indicate long-acting dose should be increased.
▼ Falling fasting glucose of 30 mg/dL or more or days with glucose < 70 mg/dL may indicate long-acting dose should be decreased.

MEAL ASSESSMENT



In Summary

- There are several CGM, connected pen and insulin pump options, and the DCES can help PWD select the best device for their individual needs
- New era of hybrid closed loops
- No artificial pancreas yet, but we are getting closer to closing the loop
- Connected data can be used to discussion diabetes self-management with the person with diabetes and help to make meaningful changes-think DATAA

Additional Resources

Diabetes Advanced Network Access (DANAtech)	danatech.org-includes panther tools
Association of Diabetes Care and Education Specialists (ADCES) glucose monitoring resources	diabeteseducator.org/practice/educator-tools/diabetes-management-tools/self-monitoring-of-blood-glucose
diaTribe	diatribe.org
DiabetesWise and DiabetesWisePro	Diabeteswise.org https://providers.diabeteswise.org/#/
ADCES Insulin pump therapy resources	https://www.diabeteseducator.org/practice/practice-tools/diabetes-management-tools/ipt-resources
Integrated Diabetes Services	https://integrateddiabetes.com/updated-insulin-pump-comparisons-and-reviews/

Panther Tools

PANTHERTOOL™ for

CONTROL-IQ

t:slim X2 insulin pump with Control-IQ technology

OVERVIEW using C|A|R|E|S Framework

C | How it CALCULATES

- A hybrid closed-loop system that uses CGM glucose data to adjust the basal insulin delivery by increasing, decreasing or suspending programmed basal rates
- Algorithm targets glucose levels 112.5-160 mg/dL
- Automatic correction boluses up to once per hour, 60% of a calculated correction dose

A | What you can ADJUST

- Can change basal rates, I:C ratios, correction factors
- CANNOT change active insulin time (5 hours) or correction bolus target (110 mg/dL)
- "Exercise Activity" targets glucose 140-160 mg/dL (to reduce insulin delivery)
- "Sleep Activity" narrows glucose target to 112.5-120 mg/dL and prevents automated correction doses overnight.

R | When to REVERT to open-loop

The system stays in hybrid closed-loop all the time except when CGM data is not available. Users must turn off Control-IQ if they want to use temporary basal rates.

E | How to EDUCATE

See PANTHERPOINTERS below as well as EDUCATE-bullets found under STEP 3.

S | SENSOR/SHARE characteristics

- Dexcom G6 sensor and transmitter: 10 day sensor life, factory calibrated, can be used for diabetes management decisions without BG check.
- User can connect Dexcom transmitter to the Dexcom G6 app on a phone and share data with others using Dexcom Follow app.
- Sensor glucose levels auto-populate into bolus calculator

PANTHERTOOL™ for

OMNIPOD® 5

Automated Insulin Delivery System

INSTRUCTIONS FOR USE

1. Download user's device to My.Glooko.com → Set report settings to Target Range 70-180 mg/dL
2. Create reports → 2 weeks → Select: a. CGM Summary; b. Week View; and c. Devices
3. Follow this worksheet for step-by-step guidance on clinical assessment, user education and insulin dose adjustments.

STEP 1 **BIG PICTURE** (PATTERNS)
→ STEP 2 **SMALL PICTURE** (REASONS)
→ STEP 3 **PLAN** (SOLUTIONS)

OVERVIEW using C|A|R|E|S Framework

C | How it CALCULATES

- Automated basal insulin delivery calculated from total daily insulin, which is updated with each Pod change (adaptive basal rate).
- Calculates dose of insulin every 5 min based on glucose levels predicted 60 minutes into future.

A | What you can ADJUST

- Can adjust the algorithm's Target Glucose (110, 120, 130, 140, 150 mg/dL) for adaptive basal rate.
- Can adjust I:C ratios, correction factors, active insulin time for bolus settings.
- Cannot change basal rates (programmed basal rates are not used in Automated Mode).

R | When to REVERT to open-loop

- System may revert to Automated Mode: Limited (static basal rate determined by system; not based on CGM value/trend) for 2 reasons:
  1. If CGM stops communicating with Pod for 20 min. Will resume full automation when CGM returns.
  2. If an Automated Delivery Restriction alarm occurs (insulin delivery suspended or at max delivery too long). Alarm must be cleared by user and enter Manual Mode for 5 min. Can turn Automated Mode back on after 5 minutes.

E | How to EDUCATE

- Bolus before eating, ideally 10-15 minutes prior.
- Tap Use CGM in bolus calculator to add glucose value and trend into bolus calculator.
- Treat mild hypoglycemia with 5-10g carb to avoid rebound hyperglycemia and WAIT 15 min before re-treating to give glucose time to rise.
- Infusion site failure: Check ketones and replace Pod if

S | SENSOR/SHARE characteristics

- Dexcom G6 which requires no calibrations.
- Must use G6 mobile app on smartphone to start CGM sensor (cannot use Dexcom receiver or Omnipod 5 Controller).
- Can use Dexcom Share for remote monitoring of CGM data.

PANTHERPOINTERS™ FOR CLINICIANS

1. Focus on behavior: Wearing the CGM consistently, giving all boluses, etc.
2. When adjusting insulin pump settings, focus primarily on Target Glucose and I:C ratios.
3. To make system more aggressive: Lower the Target Glucose, encourage user to give more boluses and intensify bolus settings (e.g. I:C ratio) to increase total daily insulin (which drives the automation calculation).
4. Avoid overthinking the automated basal delivery. Focus on the overall Time in Range (TIR), and optimizing system use, bolus behaviors and bolus doses.

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Cleveland Clinic

Every life deserves world class care.

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