Challenges and Recent Progress in the Development of Continuous Glucose Monitoring :Closed loop system.

Jeffrey S. Freeman DO FACOI FNLA
Professor of Internal Medicine
Chairman Division of Endocrinology
Philadelphia College of Osteopathic
of Osteopathic Medicine

Disclosures

Novo Nordisk – Speaker Honoraria

Bayer – Speaker Honoraria

Question 1

- 1. Which is true regarding the TSlimx2 with Control IQ?

  A. only change basal rates

  B. only change bolus rates

  C. is recommended in pregnancy

  D. optional sleep and activity setting *

Question 2

- Which statement is true?

  A. Minimed 670 G does not have its own sensor system

  B. Dexcom G6 requires calibration

  C. Free Style Libre 2 System is approved for ages 4 and higher and has high and low alarms

Question 3

- 3. Which statement is true?

A. Closed loop systems are in development for future insulin delivery

B. Closed loop systems are available, but in a very limited application

C. Closed loop systems are readily available with some restrictions in the general diabetes population *

Question 4

- 4. Which statement is true?

The Libre first generation differs from the Libre 2 because:

A. it measures blood glucose not interstitial glucose

B. it is 14 day and the Libre 2 is 21 days *

C. it does not have alarms

Question 5

- 5. True or False?
  According to the Diamond Study there was no difference with glucose variability in the CGM vs SMBG group, but significant difference in Hgb A1C.

Learning Objectives

- Review available diabetes technologies to manage patients with diabetes
- Discuss how CGMs, connected pens, insulin pumps and integrated devices can be applied in the shared clinical-decision making process to better manage patients with diabetes
- Apply diabetes technology skills to patient management.

References

1. 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.

1. Krakauer M, Botero JF, Lavalle-González FJ, Proietti A, Barbieri DE. A review of flash glucose monitoring in type 2 diabetes. Diabetol Metab Syndr. 2021 Apr 9;13(1):42. doi: 10.1186/s13098-021-00654-3. PMID: 33836819; PMCID: PMC8035716.

1. Umpierrez 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.

Resources

For a copy of these slides, additional diabetes education and resources, please visit https://aace.com/diabetes-technology.

Why Consider Using Continuous Glucose Monitoring (CGM)?

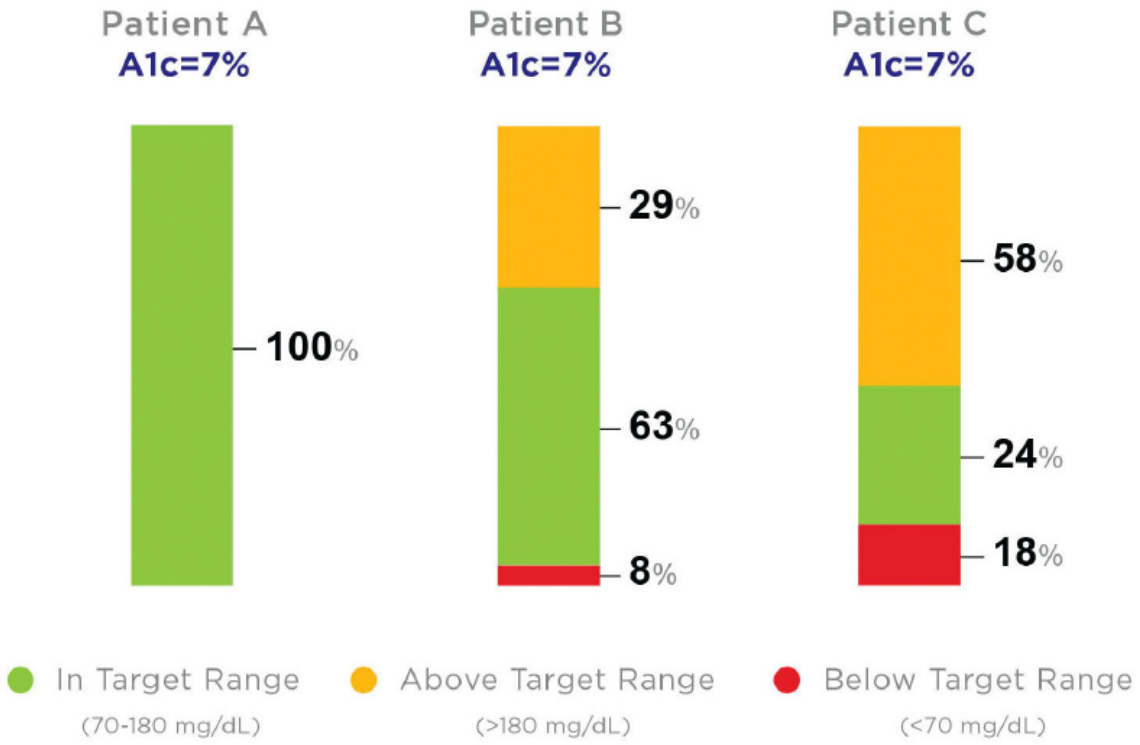
- In 1993 the DCCT established the “A1C” as the gold standard for estimating diabetes complication risk
- Despite the introduction of 18 new therapeutic interventions, only 50% of patients are able to achieve their targeted glycemic goals
- Patients are frustrated by glycemic variability - caused by lack of insulin secretion and excess excretion of glucagon
- The rate limiting step to diabetes management is hypoglycemia
- Identifying interventions which can add value to A1C interpretation and maintain “in-target” glucose values would improve patient adherence and reduce the occurrence of “dysglycemia”

Hirsch IB, Verderese CA. PROFESSIONAL FLASH CONTINUOUS GLUCOSE MONITORING WITH AMBULATORY GLUCOSE PROFILE REPORTING TO SUPPLEMENT A1C: RATIONALE AND PRACTICAL IMPLEMENTATION. Endocr Pract. 2017 Nov;23(11):1333-1344.

AACE®

Not All A1cs Are Created Equal

HbA1c only provides a broad look at a patient's glucose history. Time in Range provides more actionable information than A1c alone and should complement A1c.[1]



Law of averages!!

Not actual patient data; for illustrative purposes only.

1. Battelino T, Danne T, Berganstal RM, et al. Clinical targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range. *Diabetes Care.* 2019;42(8):1593-1603.

Value of CGM In Patients With T2DM

- Discover previously unknown hyper and hypoglycemic events
- Measure glycemic control directly rather than via the surrogate metric of A1C
- Observe metrics such as glycemic variability, time spent within, below or above targeted glucose range throughout the day
- Determine the duration and severity of unrecognized hypoglycemia, especially nocturnal
- Provide actionable information derived from the CGM report
- Analyze glucose effects of targeted pharmacologic interventions (both fasting and post-meal glucose values)
- Evaluate the effect of exercise on glycemic control
- Provide behavioral interventions based on real-time glycemic values

Vigersky R, Shrivastav M. Role of continuous glucose monitoring for type 2 in diabetes management and research. J Diabetes Complications. 2017 Jan;31(1):280-287.

Who Benefits From Routine Use Of Continuous CGM?

- ALL patients treated with intensive insulin therapy (MDI or insulin pumps)
- ALL patients with “problematic hypoglycemia” (Frequent, nocturnal, hypoglycemia unawareness)
- Children and adolescents with T1DM
- Pregnant women with either T1DM or T2DM (treated with insulin)
- Patients with gestational diabetes treated with insulin
- Consider CGM for patients with T2DM who are treated with less intensive therapy

Yes

ALL

Grunberger G, Sherr J, Allende M, Blevins T, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus. Endocr Pract. 2021 Jun;27(6):505-537.

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CONTINUOUS GLUCOSE MONITORS

ABBOTT FREESTYLE LIBRE SENSOR

DEXCOM G6 SENSOR

GUARDIAN PUMP AND SENSOR

Professional vs Personal CGM

PROFESSIONAL CGM[a]

- Use in the office
- The CGM device is put on the patient
- Patient comes back later
- Download the information
- Professional CGM is useful for improving glycemic control in a low socioeconomic population with limited access to current technology
  - Can lower A1C 0.8 % with intermittent use
  - Can encourage lifestyle changes and medication adherence

PERSONAL CGM[a]

- What the patient uses
- Patient uses the information to make decisions on their insulin, when to eat, etc
- Provides alarms for lows and highs
- Can increase engagement in diabetes self-management

CGM technology can be extremely important in lowering HbA_{1c} and minimizing hypoglycemia in patients on MDI with T1D[b,c]

a. Blevins TC. Professional continuous glucose monitoring in clinical practice 2010. J Diabetes Sci Technol. 2010 Mar 1;4(2):440-56.
b. Beck RW, Riddlesworth T, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. JAMA. 2017 Jan 24;317(4):371-378.
b. Sulman H, et al. Diabetes 2018 Jul; 67(Supplement 1)
c. Lind M, Polonsky W, Hirsch IB, et al. Continuous Glucose Monitoring vs Conventional Therapy for Glycemic Control in Adults With Type 1 Diabetes Treated With Multiple Daily Insulin Injections: The GOLD Randomized Clinical Trial. JAMA. 2017 Jan 24;317(4):379-387.

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From: A review of flash glucose monitoring in type 2 diabetes

Study (population)	Effect of:	HbA1c (%)
Fokkert et al. [20] T1D, n = 1054; T2D, n = 223; Other, n = 88	Before vs. after FGMS use on estimated HbA1c	At baseline: 8.0% (95% CI 7.9–8.1) At 6 months: 7.6% (95% CI 7.5–7.7); $P < 0.001$ *vs.* baseline At 12 months: 7.6% (95% CI 7.6–7.7); $P < 0.001$ *vs.* baseline
Eeg-Olofsson et al. [21] T1D, n = 8316; T2D, n = 538	Before vs. after FGMS use on HbA1c (method of measurement not specified)	T1D: 8.1% at baseline. Mean change –0.33% (95% CI − 0.36 to − 0.31); $P < 0.0001$ T2D: 8.6% at baseline. Mean change –0.52% (95% CI − 0.63 to − 0.40); $P < 0.0001$
Evans et al. [22] Meta-analysis of 29 studies; n = 1723 with T1D or T2D	FGMS use on laboratory HbA1c	In adults at 2–4 months: mean change − 0.56% (95% CI − 0.76 to − 0.36) In children and adolescents at 2–4 months: mean change − 0.54% (95% CI − 0.84 to − 0.23)
Ish-Shalom et al. [23] T1D, n = 6; T2D, n = 25	FGMS use on HbA1c (method of measurement not specified)	In patients with HbA1c ≥ 7.5% At 8 weeks: mean change − 1.33 ± 0.29%; $P < 0.0001$ At 24 weeks: mean change − 1.21 ± 0.42%; $P = 0.009$
Dunn et al. [24] n > 50,000	↑ Scanning frequency on estimated HbA1c	Highest (48.1 scans/day) vs. lowest (4.4 scans/day) scan rate group: 6.7% (95% CI 6.7–6.8) vs. 8.0% (95% CI 7.9–8.0; $P < 0.001$
Gomez-Peralta et al. [26] n = 22,949	↑ Scanning frequency on estimated HbA1c	Highest (39.6 scans/day) vs. lowest (3.9 scans/day) scan rate group: 6.9% (95% CI 6.9–7.0) vs. 8.0% (95% CI 8.0–8.1); $P < 0.001$
Calliari et al. [27] Brazil: 17,691 readers and 147,166 sensors Worldwide: 688,640 readers and 7,329,052 sensors	↑ Scanning frequency on estimated HbA1c	Brazil: Highest (43.1 scans/day) *vs.* lowest (3.6 scans/day) scan rate group: 6.7% (95% CI 6.6–6.8) vs. 7.6% (95% CI 7.4–7.7); $P < 0.01$ Worldwide: Highest (37.8 scans/day) *vs.* lowest (3.4 scans/day) scan rate group: 6.7% (95% CI 6.7–6.7) vs. 8.1% (95% CI 8.1–8.2); $P < 0.01$

GlucoWatch® Biographer

First To Receive FDA Approval

Continuous Glucose Monitors

- Interstitial glucose sensor (size of an eyelash) is inserted manually
- Data from the interstitial sensor is transmitted to a "reader", insulin pump or app and displayed to the user
- CGM Available Data:
  - Current glucose level
  - Glucose trends related to meals, exercise, medication, sleep, travel
  - Glucose directional trends
  - Alarms for glucose levels < 70 or > 240 mg/dL

Dexcom 6 Transmitter (battery)

Abbott Freestyle Libre Sensor

Dexcom 6 Sensor

Guardian Medtronic pump and sensor

Unger J, Kushner P, Anderson JE. Practical guidance for using the Freestyle Libre Flash continuous glucose monitoring in primary care. Postgraduate Medicine.

FreeStyle Libre 2 system

- ✓ Continuous glucose monitoring system FDA-cleared for adults and children with diabetes ages 4 years and above
- ✓ Now with optional, real-time glucose alarms that notify you if you go too low or too high*
- ✓ 14-day accuracy[1] for adults and children
- ✓ Easily check your glucose levels with scan instead of a fingerstick†
- ✓ Notifications will only be received when alarms are turned on and the sensor is within 20 feet of the reading device.

Libre 2 iOS app, FDA approved 8.2.2021 with compatible iPhones

Larger doses of Vitamin C (greater than 500mg) can alter readings.

How CGM Can Help Reduce Diabetes Management Challenges

Moving beyond A1c

Using a combination of metrics allows for a more complete picture of glucose profile[1]

A1c + AGP (Ambulatory Glucose Profile)

Combining each patient's A1c with their ambulatory glucose profile (AGP) uncovers critical daily patterns

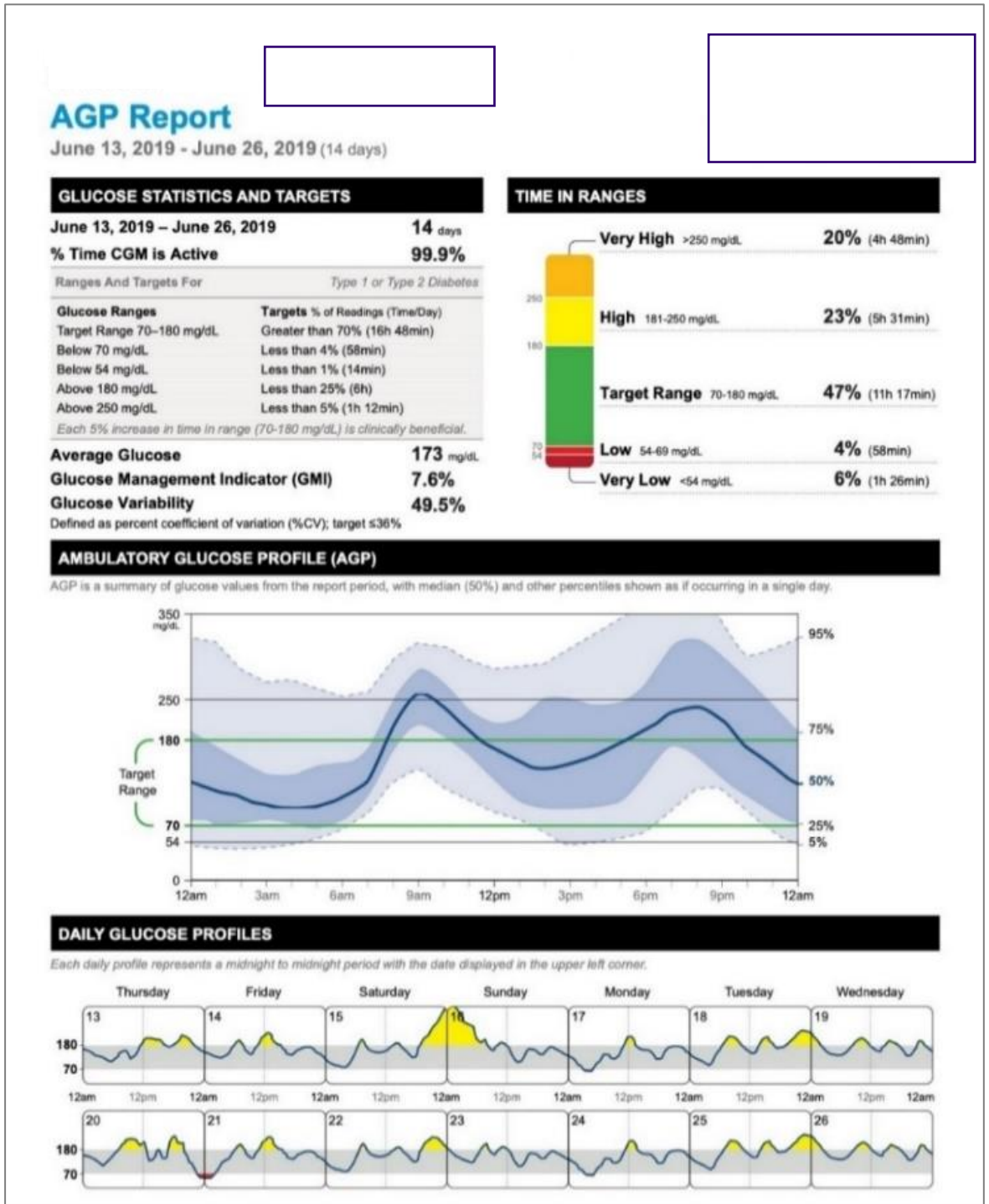
TIR (Time in Range) + TBR (Time below range)

Monitoring TIR and TBR glucose variability helps show how closely readings of an individual patient fall within target range, or below, in hypoglycemia

Glucose data

Additional access to acute, daily, and long-term (90 days) data allows for more informed treatment decisions

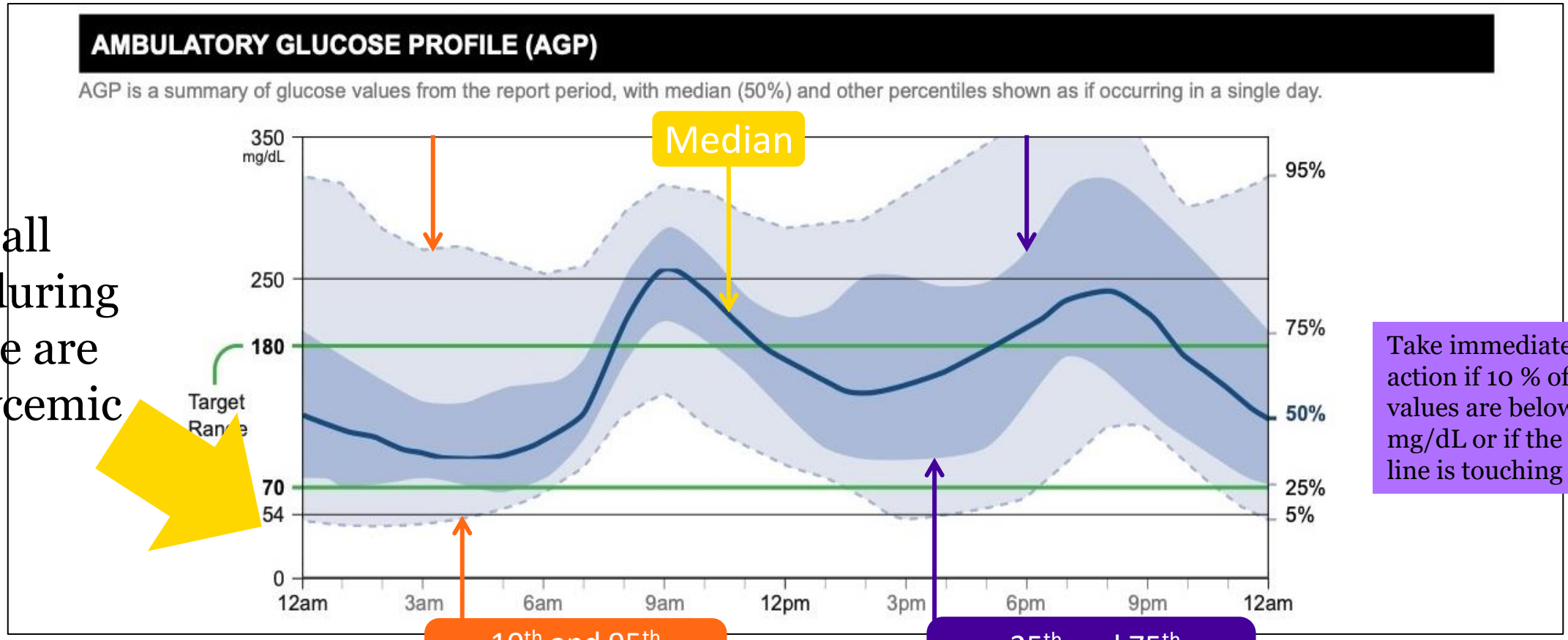
AGP provides a standardized visualization that condenses glucose data generated from GGM over several days or weeks into a single, 24-hour window.



1. Battelino T, Danne T, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. Diabetes Care. 2019 Aug;42(8):1593-1603.

Ambulatory Glucose Profile (AGP)

Illustrates trends, patterns and glycemic variability



10 % of all values during this time are hypoglycemic

Take immediate action if 10 % of the values are below 54 mg/dL or if the 25 % line is touching 70.

Not based on real patient data. Illustrative only.

10th and 95th Percentile Curves

90% of all values

25th and 75th Percentile Curves

50 % of all values fall within the interquartile range

Note: Other reports will still have 10% - 90% percentiles for the AGP graphs until a later release.

Dexcom G6® CGM

No Fingersticks Required

- **No fingerstick calibrations.**
- Users can enter optional fingersticks in the case of an inaccurate sensor, however this seems to be discouraged.
- **One-button insertion device**
- 28% **smaller profile transmitter** (about two-thirds of the original size)
- **10-day wear time;** Mandatory shutoff once the 10-day wear time is up since the CGM is factory-calibrated
- No acetaminophen interference
- The Dexcom G6 CGM transmitter can only be paired with one medical device (either a Dexcom receiver or t:slim X2 Pump) and one consumer device (phone or tablet) at the same time.
- Allows remote viewing of glucose levels, trends and data between the person with diabetes and their spouse, grandparent or other loved ones from an Android, Apple iPhone® or iPod touch®**
- **Approved for ages 2 years and older.**

****check DexCom website for phone compatibility.**

Clarity Report

2% Very High
15% High
80% In Range
2% Low
<1% Very Low

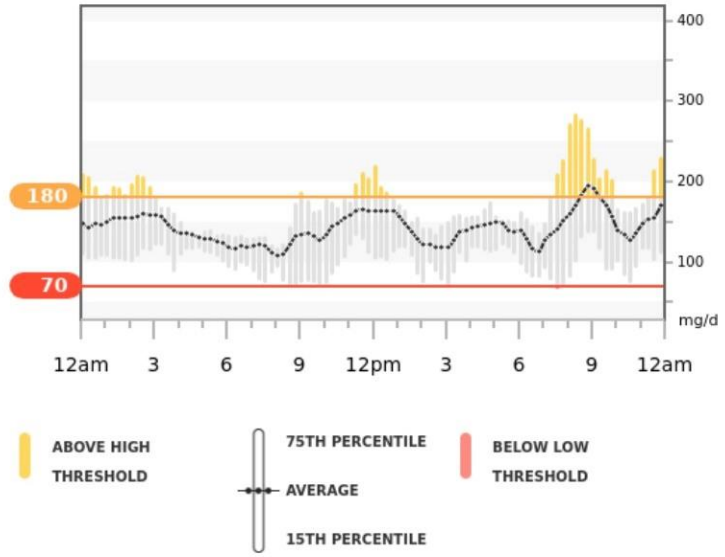
Increase since last week: +2%
Target Range: 70-180 mg/dL

Average glucose	Standard deviation
142 mg/dL	**44** mg/dL

Patterns

No patterns were found for this date range.

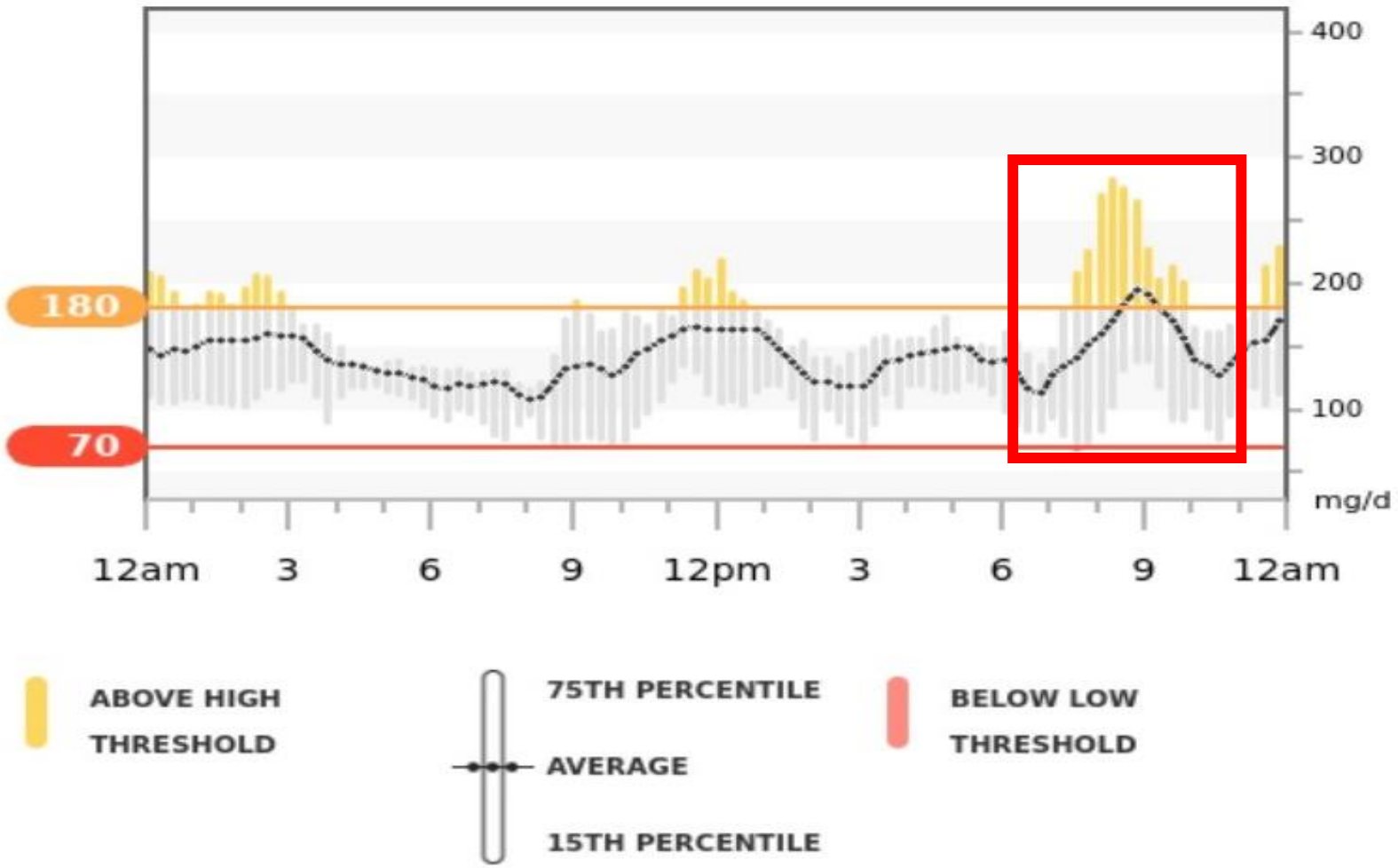
Trends



Visit Dexcom CLARITY on the web for all your CGM glucose reports.

You signed up for this Dexcom CLARITY Weekly Summary with the Dexcom CLARITY app. Unsubscribe

Trends



Visit Dexcom CLARITY on the web for all your CGM glucose reports.

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What's coming?

Not FDA Approved

Dexcom G7 CGM

This latest model of the Dexcom CGM is set to bring a significant form-factor change: a combined sensor and transmitter design.

Features

- ✓ **Fully disposable**
- ✓ **Wear time: 14-15days, no fingersticks required**
- ✓ **Thinner**
- ✓ **Integration with software features.**

Dexcom plans to submit the G7 for FDA approval in early 2021 and plans for a limited launch late in the year.

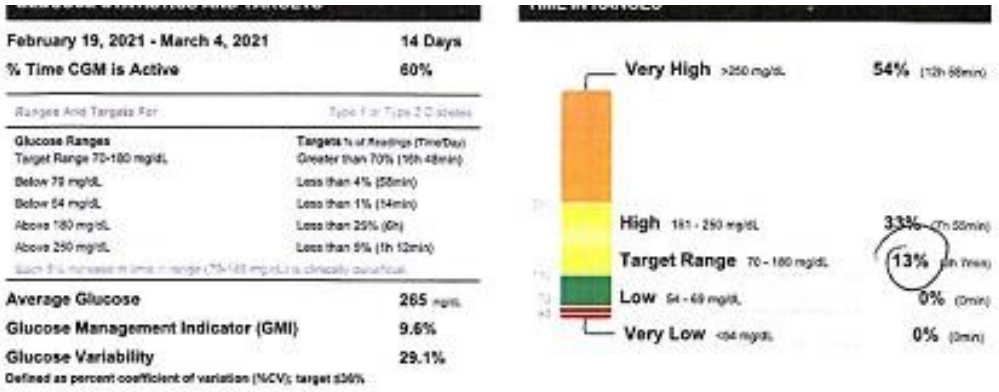
Reference:
https/www.danatech.org/news/diabetesmine-new-diabetes-technology-what-to-expect-in-2021/
https://www.healthline.com/diabetesmine/new-diabetes-technology-coming-in-2021

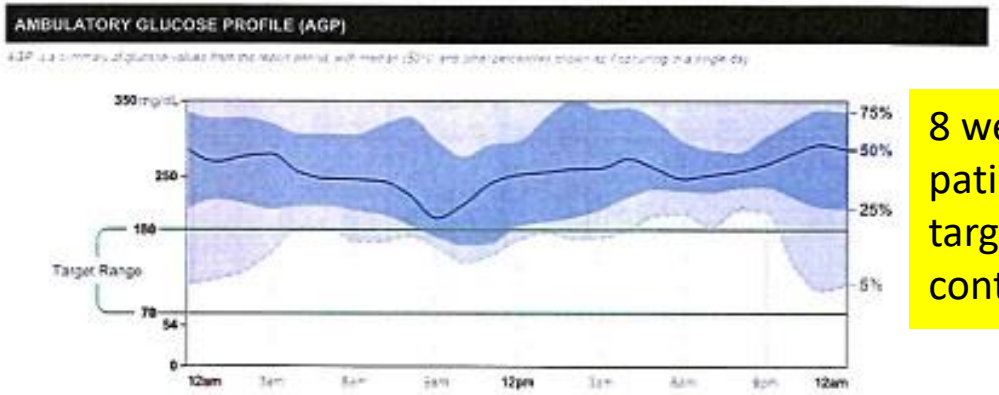
Table 2 Metrics used in CGM

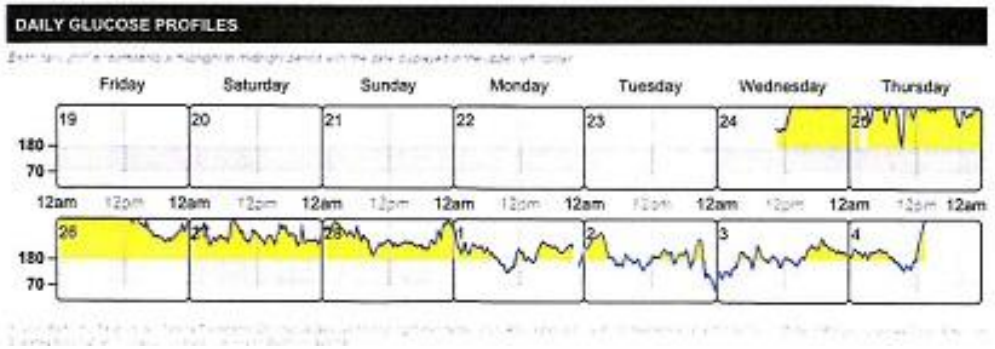
From: Continuous Glucose Monitoring: A Brief Review for Primary Care Practitioners

Metrics	Definition	Advantages/limitations
Standard deviation [45]	A measure of variance of glucose levels	Directly calculated by all devices
Coefficient of variation [45]	A measure of short-term within-day variability, independent of the mean value; percentiles represent deviations about the median, thus distinguishing stable from labile glycemic control	Easy to calculate from standard deviation and mean glucose level
Mean amplitude of glucose excursions [45]	A measure of short-term within-day variability	Obtained indirectly, through calculation
Precision absolute relative deviation [46]	Indicates the similarity of two sensor traces simultaneously recorded from a single CGM system worn by one subject	Easy to compute and interpret, but lacks detailed information
Continuous glucose-error grid analysis [46]	Provides a clinical assessment of accuracy by comparing CGM and SMBG results	Readings must be obtained at least every 15 min
Mean absolute relative difference [47]	Indicates the similarity of CGM and reference blood glucose results; expressed as the average of absolute errors between all CGM values and matched reference values	Provides a single value that represents the overall accuracy of the CGM system

Lee (3) Before and After

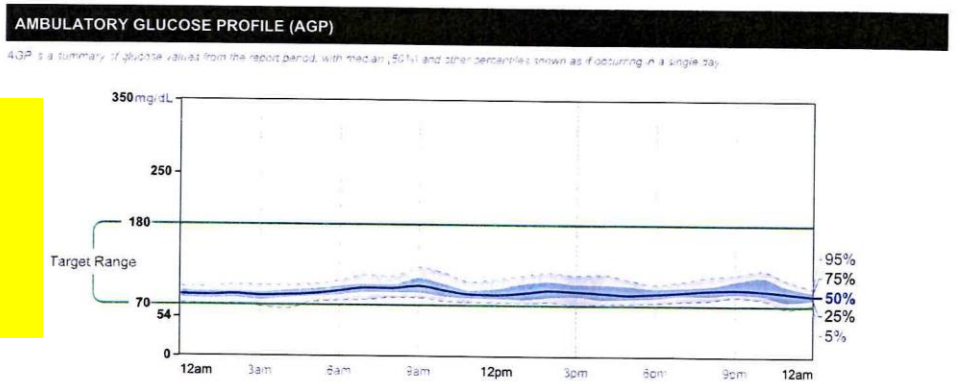


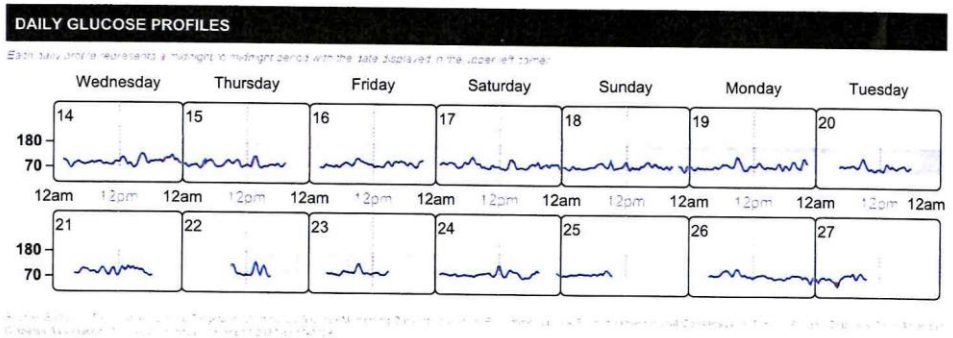




No pharmacotherapy 3/4/21

8 weeks until patient achieved target glycemic control!





4/29/21: Liraglutide 1.2 mg/d + insulin degludec 10 units/d

Addressing Problematic Glycemic Patterns

Hypoglycemia (> 4 %)

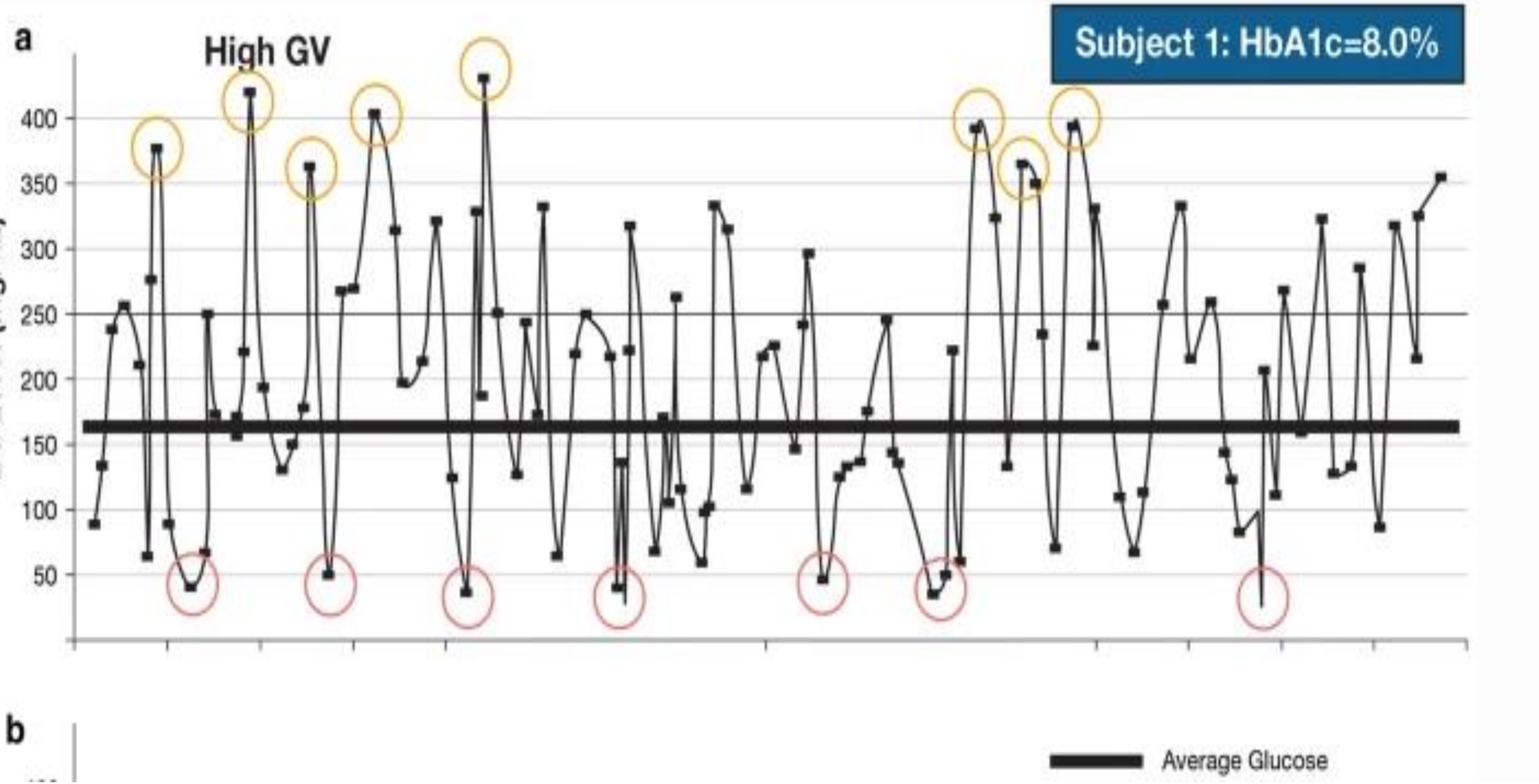
- Review potential meal skips
- Stop or reduce SUs
- Consider use of meds which do not increase likelihood of hypoglycemia
- Reduce basal or premeal insulin dose
- Modify exercise timing related to insulin dosing
- Reduce or stop alcohol consumption
- Mismatch of prandial insulin dose and carbohydrate intake

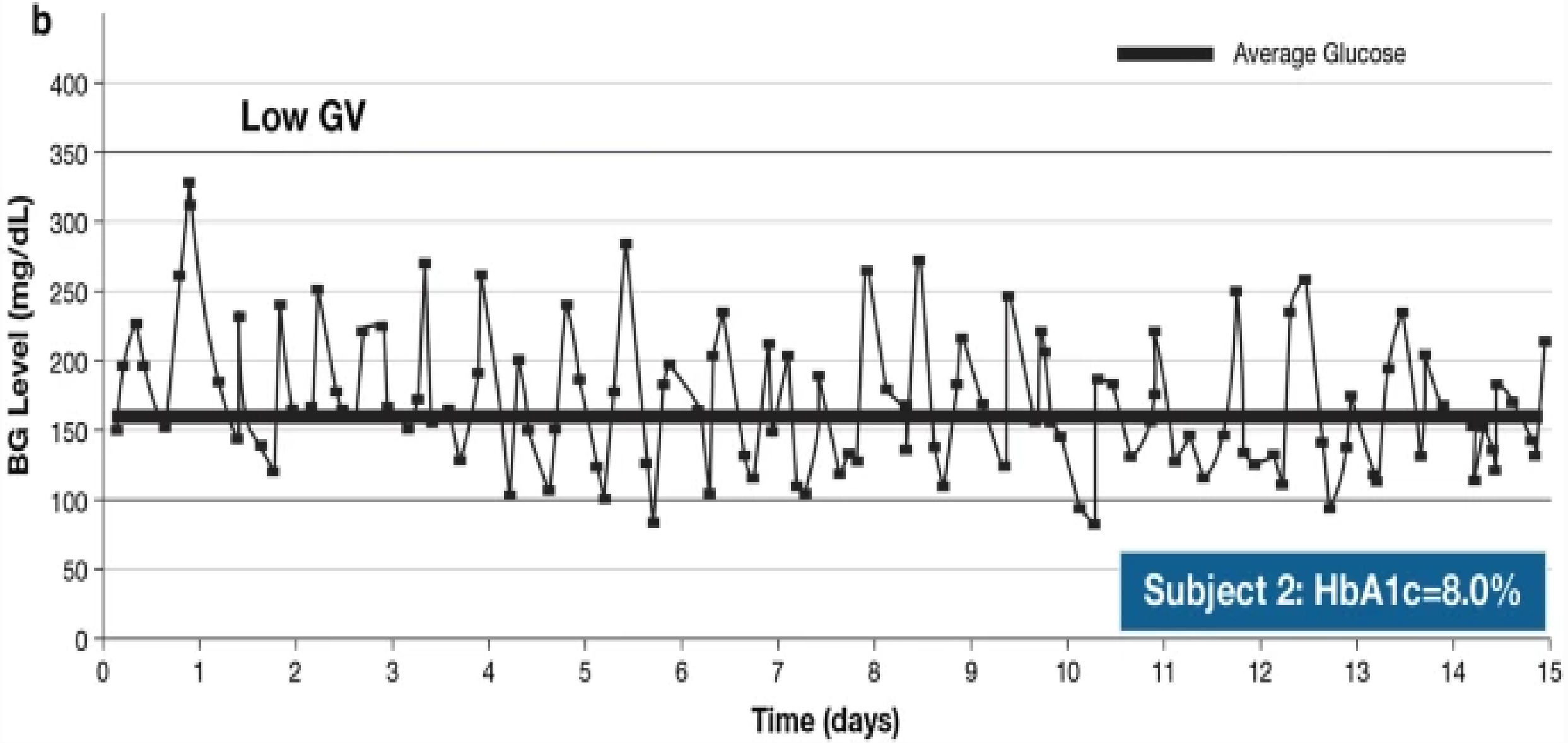
Time in Range < 70 %

- Discuss med adherence
- Add basal insulin, GLP-1RA, SGLT2, or prandial insulin
- Discuss carb counting (identification) or meal size as related to prescribed insulin dosing

Unger J, Kushner P, Anderson JE. Practical guidance for using the FreeStyle Libre flash continuous glucose monitoring in primary care. Postgrad Med. 2020 May;132(4):305-313.

ig. 1


a
High GV
Subject 1: HbA1c=8.0%
400
350
300
250
200
150
100
50
b
Average Glucose



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

Tricks to Successful Initiation of CGM In Primary Care

Role of the Clinician

- Make it simple!
- Put the first sensor on in the office for the patient. Subsequent sensors can be placed by the patient with guidance from MA
- Explain how the CGM may benefit patients' diabetes control
  - More time in prescribed range
  - Reduced incidence of hypoglycemia
  - Improved glycemic variability
  - Access to data while sleeping
  - Improve A1C
  - Reduce risk of hospitalizations
  - Improved rates of work absenteeism

Role of the Patient

- Confidence in applying the sensor appropriately
- Scan frequently
- Minimize gaps in sensor wear
- Contact Customer Service if sensors fail or fall off
- Bring data to each visit
- Understand glycemic patterns related to food, sleep, exercise, travel, etc.

Pt CB

AGP Report

April 15, 2021 - April 28, 2021 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

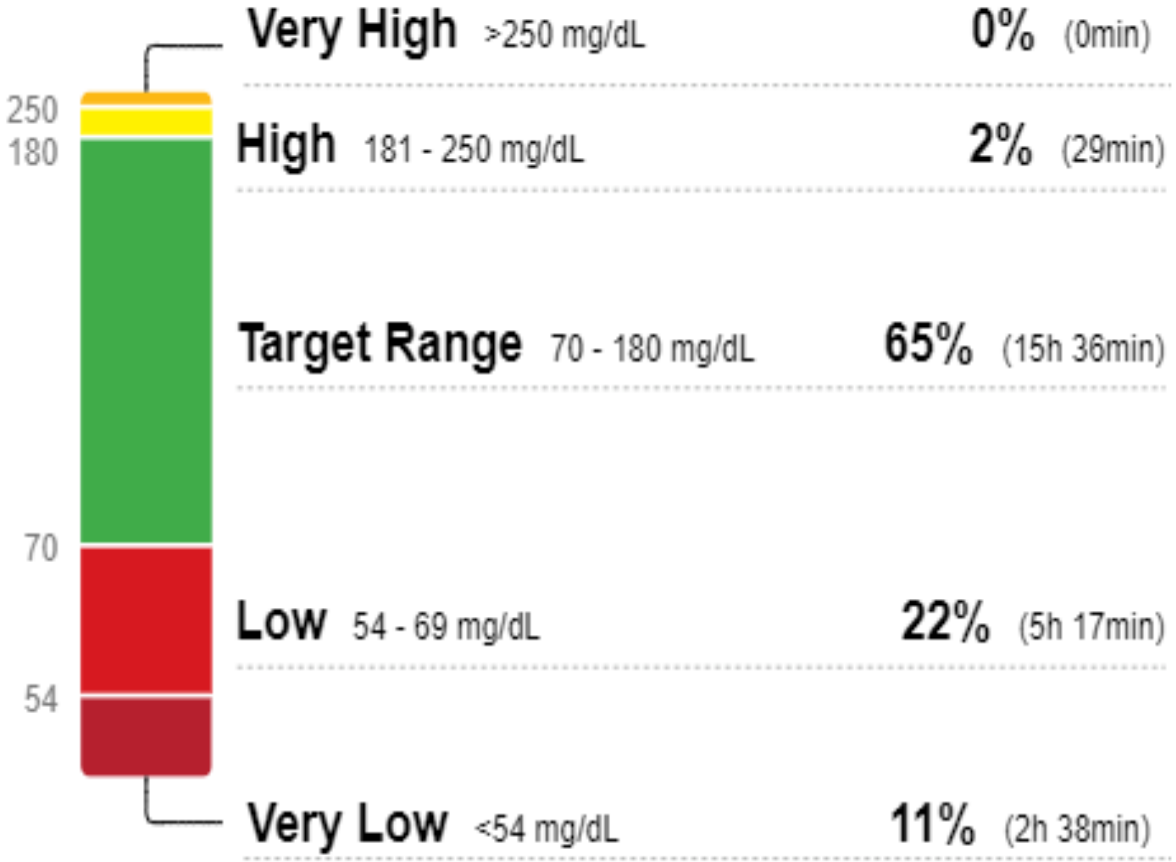
April 15, 2021 - April 28, 2021	14 Days
% Time CGM is Active	96%

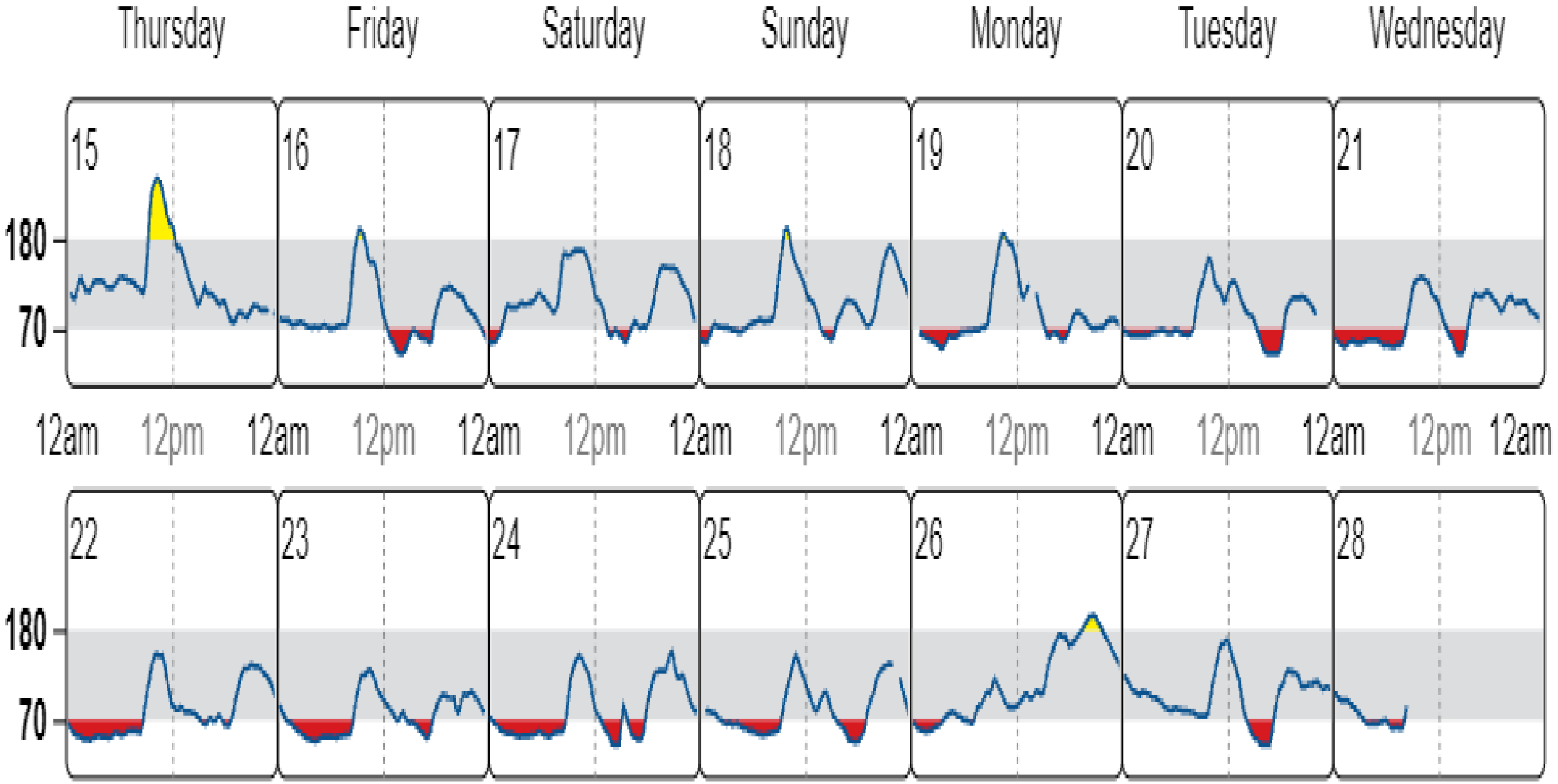
Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges Target Range 70-180 mg/dL	**Targets** % of Readings (Time/Day) Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)
Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.	

Average Glucose	93 mg/dL
Glucose Management Indicator (GMI)	5.5%
Glucose Variability	39.5%

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

TIME IN RANGES




Thursday
Friday
Saturday
Sunday
Monday
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Wednesday
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16
17
18
19
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21
180
70
12am
12pm
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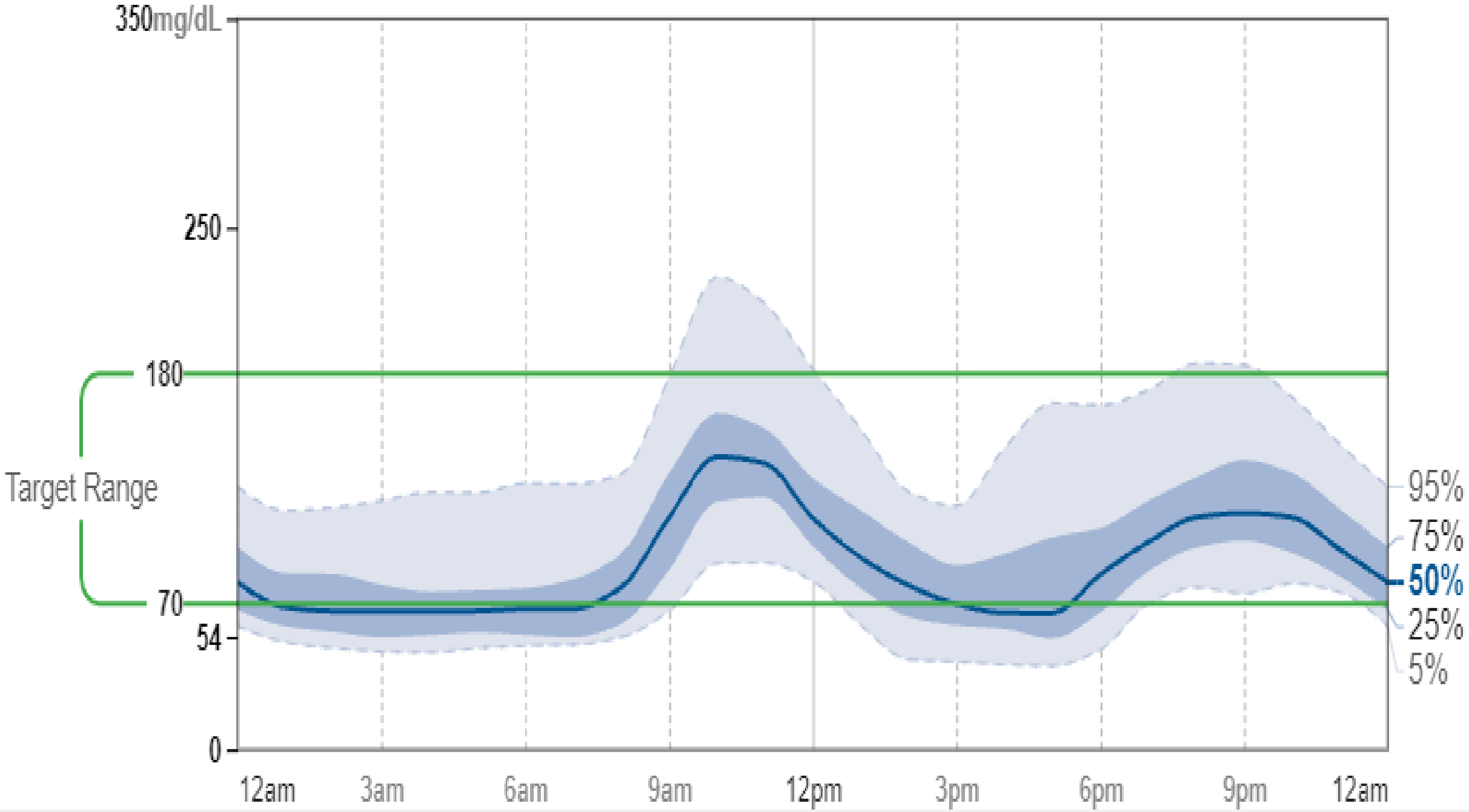
180
70


350mg/dL
250
180
Target Range
70
54
0
12am
3am
6am
9am
12pm
3pm
6pm
9pm
12am
95%
75%
50%
25%
5%

AGP Report

June 1, 2021 - June 14, 2021 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

June 1, 2021 - June 14, 2021	14 Days
% Time CGM is Active	93%

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	110 mg/dL
Glucose Management Indicator (GMI)	5.9%
Glucose Variability	33.4%

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

TIME IN RANGES

Very High	>250 mg/dL	0%	(0min)
High	181 - 250 mg/dL	5%	(1h 12min)
Target Range	70 - 180 mg/dL	82%	(19h 41min)
Low	54 - 69 mg/dL	10%	(2h 24min)
Very Low	<54 mg/dL	3%	(43min)

What's coming?

Not FDA Approved

Abbott FreeStyle Libre 3

Features:

- ✓ no longer require any sensor scanning to provide real-time glucose readings.
- ✓ real-time glucose reading every minute, displaying that result on the compatible mobile app on iPhone or Android.
- ✓ continuous stream of data allows optional alerts for high and low blood sugars, along with glucose results.

Libre 3 likely to be submitted to the FDA during 2021.

Reference:
https://www.danatech.org/news/diabetesmine-new-diabetes-technology-what-to-expect-in-2021/
https://www.healthline.com/diabetesmine/new-diabetes-technology-coming-in-2021

Smart Pens

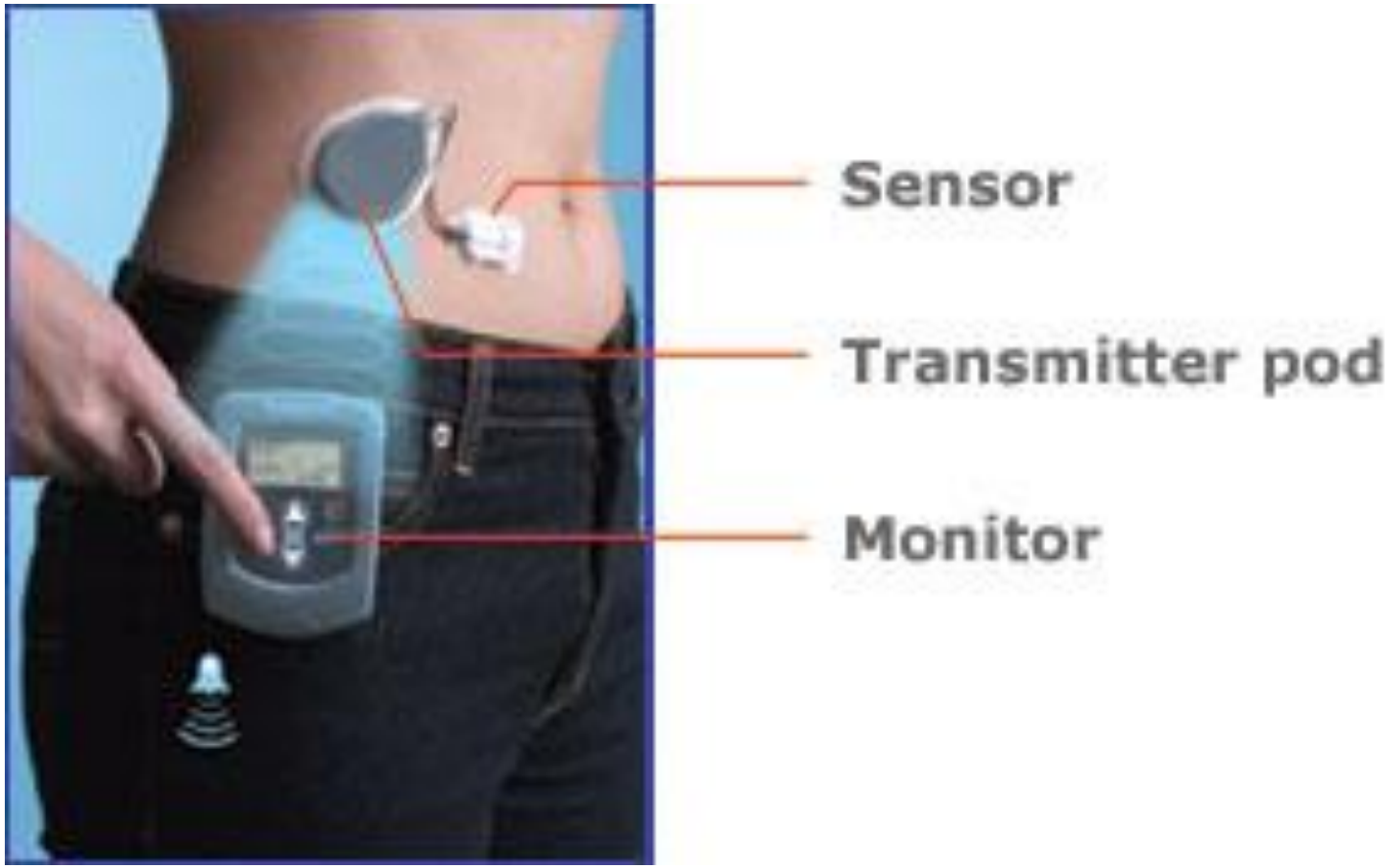
- Smart pens automatically track insulin doses and calculate active insulin
- Improve TIR without increasing hypoglycemia risk
- Real world study of 1736 patients before and after using Smart Pen increased TIR by 2.3 % in patients with a GMI > 8 % and 5 % for patients with a GMI > 9.5 %
- Improved glycemic control with less injections given (less stacking)

Patch Pumps

Omnipod Wireless Pump and PDM

V-Go Insulin Pump

Guardian RT System



What's coming?

Not FDA Approved

Future: Project Duo:

- **Combined sensor & infusion set**
- **Single insertion**
- **1 week wear**

Connecting the Insulin Pump and CGM

Tandem Complete IQ with Dexcom 6 CGM

Medtronic 670 G plus Guardian CGM

Automated Insulin Delivery Devices (AID)

- Strongly recommended for all persons with T1DM
- Devices have been shown to increase TIR without causing an increased risk of hypoglycemia
- Preferred method of insulin delivery for people with diabetes and suboptimal glycemia, glycemic variability, impaired hypoglycemia awareness or who allow for permissive hyperglycemia due to their fear of hypoglycemia

Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus. Endocr Pract. 2021 Jun;27(6):505-537.

AACE®

In What Settings or Special Situations Is The Use of Diabetes Technology Useful?

- **Continuation** of CGM and or CSII should be considered in hospitalized patients without cognitive impairment
- rtCGM is recommended for people ≥ age 65 with insulin requiring diabetes to achieve improved glycemic control, reduce episodes of severe hypoglycemia and improve QOL.
  - Individualize glycemic targets in this population due to increased risk of comorbidities and long-term diabetes related complications
- Use CGM to track glucose before during and after exercise, help direct insulin and carbohydrate consumption and mitigate glycemic variability

Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus. Endocr Pract. 2021 Jun;27(6):505-537.

CPT code	Descriptor	Medicare Allowable for Arizona
95249	Patient-owned (non-professional) CGM sensor placement, hook-up, calibration, patient training, removal of sensor, and printout of recording - Requires minimum of 72 hours of data collection - Can only be billed once for the duration the patient owns the device	$55.62
95250	Professional CGM sensor placement, hook-up, calibration, patient training, removal of sensor, and printout of recording - Requires minimum of 72 hours of data collection - Can be billed once per month	$149.53
95251	CGM download and interpretation - Patient does not have to be physically in the office - Can be billed once a month - Requires minimum of 72 hours of data for review	$34.91
99091	Download and interpretation of insulin pump data - Can be billed once a month - CPT codes 95249, 95250, and 95251 cannot be billed in addition to this code	$55.77

https://www.cms.gov/medicare/physician-fee-schedule/search

JAMA Network™

From: **Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial**

JAMA. 2017;317(4):371-378. doi:10.1001/jama.2016.19975

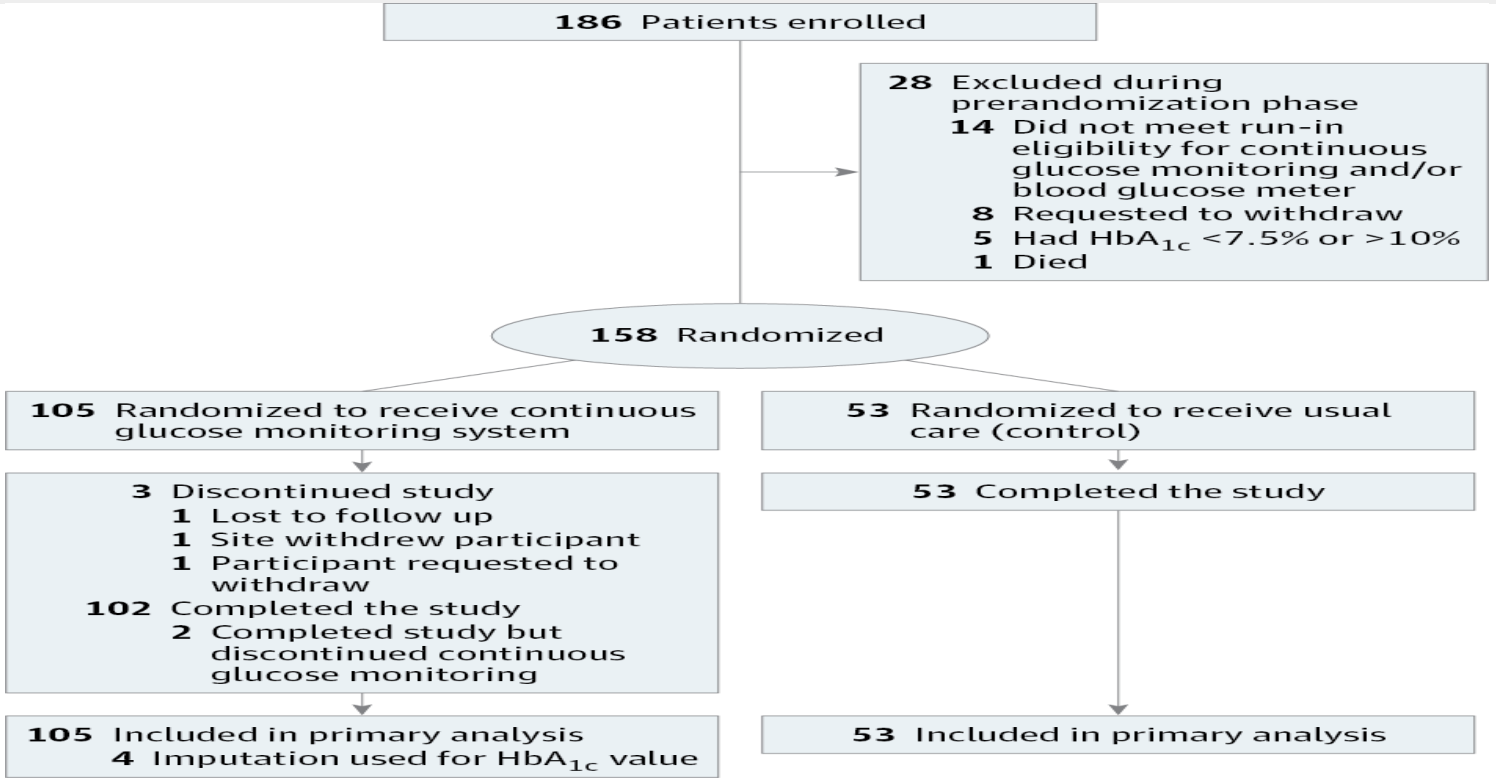


Figure Legend:

Flowchart of Continuous Glucose Monitoring Study CompletionAll enrolled participants started the run-in phase; 28 did not proceed to randomization for the reasons indicated in the figure. The number eligible for screening who did not sign the informed consent form was not recorded.

Date of download: 10/4/2021

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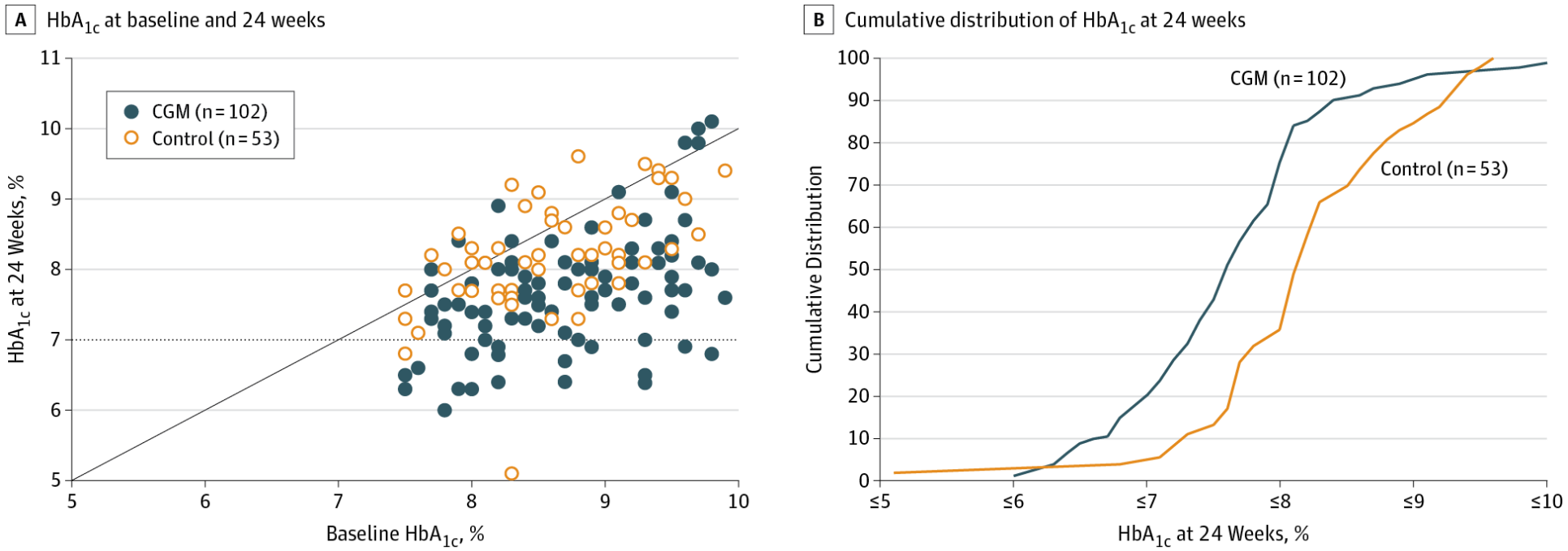

Figure Legend:

Hemoglobin A_{1c} Values at Baseline and 24 Weeks, by GroupA, Scatterplot of 24-week hemoglobin A_{1c} (HbA_{1c}) levels by baseline HbA_{1c} level. The horizontal line at 7.0% represents the American Diabetes Association HbA_{1c} goal for adults with type 1 diabetes. Points below the diagonal line represent cases in which the 24-week HbA_{1c} level was lower than the baseline HbA_{1c} level, points above the diagonal line represent cases in which the 24-week HbA_{1c} level was higher than the baseline HbA_{1c} level, and points on the diagonal line represent cases in which the 24-week and baseline HbA_{1c} values were the same. B, Cumulative distribution of 24-week HbA_{1c} values. For any given 24-week HbA_{1c} level, the percentage of cases in each treatment group with an HbA_{1c} value at that level or lower can be determined from the figure. To convert HbA_{1c} to the SI units of mmol/mol, multiply the HbA_{1c} percentage

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JAMA. 2017;317(4):371-378. doi:10.1001/jama.2016.19975

Table 3. Continuous Glucose Monitoring Metrics

	CGM Group (n = 105)	Control Group (n = 53)	CGM Group (n = 103)	Control Group (n = 53)	Mean Adjusted Difference (99% CI)[b]	*P* Value[b]
Hours of data, mean (SD)	322 (50)	325 (51)	301 (41)	301 (54)		
Prespecified secondary outcomes						
Glucose variability: coefficient of variation, mean (SD), %	42 (7)	42 (7)	38 (6)	42 (7)	−4 (−6 to −2)	<.001
Minutes per day in range 70-180 mg/dL, mean (SD)	660 (179)	650 (170)	736 (206)	650 (194)	77 (6 to 147)	.005
Hypoglycemia, median (IQR)						
Minutes per day <70 mg/dL	65 (33 to 103)	72 (35 to 136)	43 (27 to 69)	80 (36 to 111)		.002
Minutes per day <60 mg/dL	32 (15 to 61)	39 (15 to 78)	20 (9 to 30)	40 (16 to 68)		.002
Minutes per day <50 mg/dL	13 (5 to 29)	18 (4 to 39)	6 (2 to 12)	20 (4 to 42)		.001
Hyperglycemia, median (IQR)						
Minutes per day >180 mg/dL	687 (554 to 810)	725 (537 to 798)	638 (503 to 807)	740 (625 to 854)		.03
Minutes per day >250 mg/dL	301 (190 to 401)	269 (184 to 383)	223 (128 to 351)	347 (241 to 429)		<.001
Minutes per day >300 mg/dL	129 (66 to 201)	109 (71 to 204)	78 (36 to 142)	167 (89 to 226)		<.001
Prespecified exploratory outcome						
Mean glucose, mean (SD), mg/dL	187 (27)	186 (30)	180 (27)	189 (25)	−9 (−19 to 0)	.01
Post hoc outcomes, median (IQR)[c]						
Area above curve 70 mg/dL	0.5 (0.3 to 1.1)	0.7 (0.2 to 1.4)	0.3 (0.2 to 0.5)	0.7 (0.2 to 1.3)		<.001
Area under curve 180 mg/dL	34 (25 to 46)	33 (26 to 45)	27 (17 to 40)	40 (31 to 51)		<.001

Abbreviations: CGM, continuous glucose monitoring; IQR, interquartile range.

SI Conversion: to convert glucose to mmol/L, multiply the values × 0.0555.

[a] Excludes 2 participants in the CGM group with less than 72 hours of data (a prespecified condition).

[b] Treatment group comparisons made with analysis of covariance models, adjusted for the corresponding baseline value, baseline hemoglobin A_{1c} level, and clinical site as a random effect, using pooled data from 12 and 24 weeks. Because of skewed distributions for the hypoglycemia and hyperglycemia metrics (including area above the curve 70 mg/dL and area below the curve 180 mg/dL), these models were based on ranks using van der Waerden scores. $P < .01$ was considered significant to account for multiple comparisons (with 99% CI accordingly provided for the metrics that are approximately normally distributed).

[c] Area above (the glucose) curve 70 mg/dL reflects both percentage and severity of glucose values in the hypoglycemic range. Area under (the glucose) curve 180 mg/dL is the analogous measure for hyperglycemia.

Table Title:

Continuous Glucose Monitoring MetricsAbbreviations: CGM, continuous glucose monitoring; IQR, interquartile range.

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PUMPS AVAILABLE IN THE US

MEDTRONIC SERIES 670,770, SOON 880

TSLIM SERIES X2 WITH CONTROL IQ

OMNIPOD

TODAY'S PUMP THERAPY

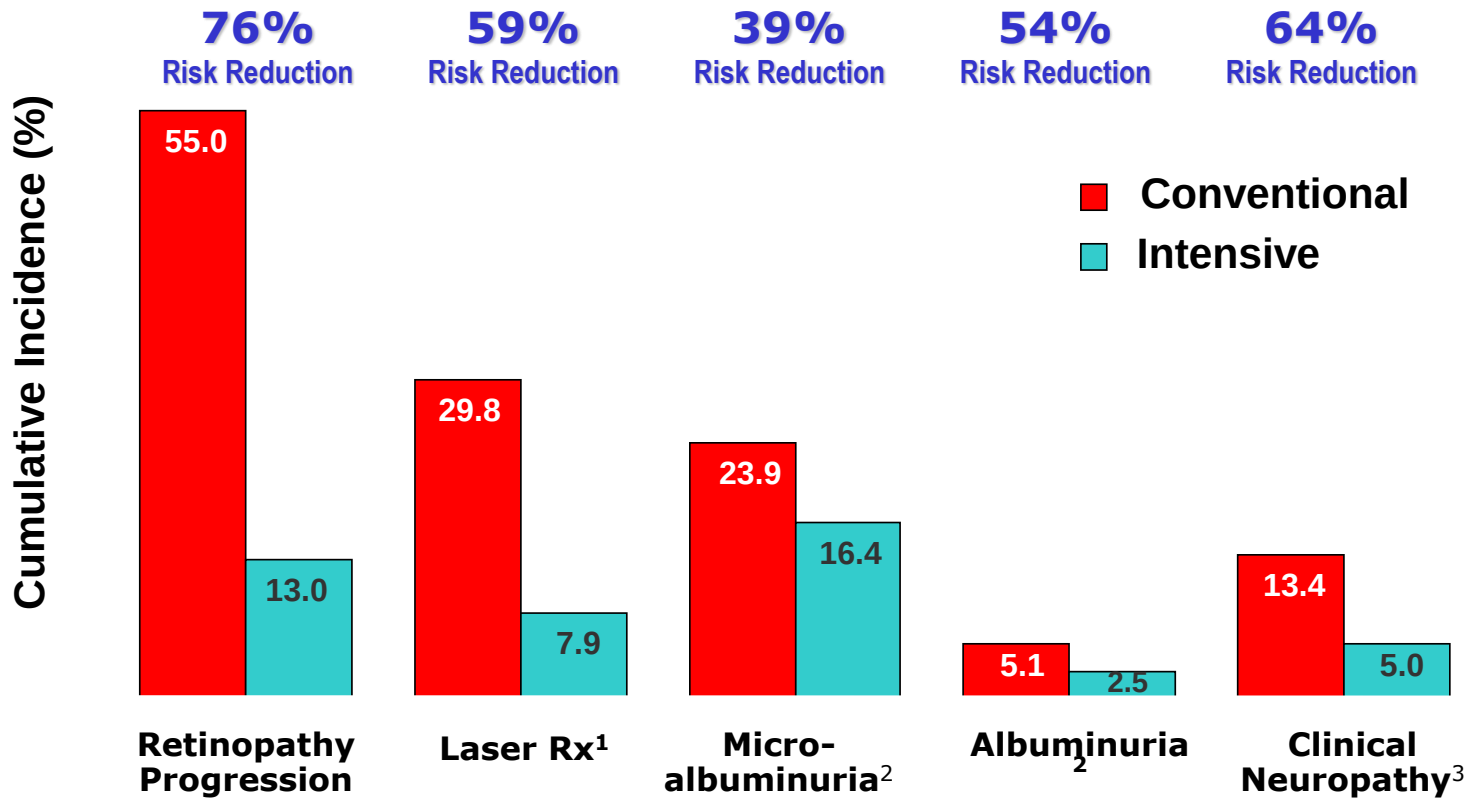
Medtronic

Omnipod

Tandem

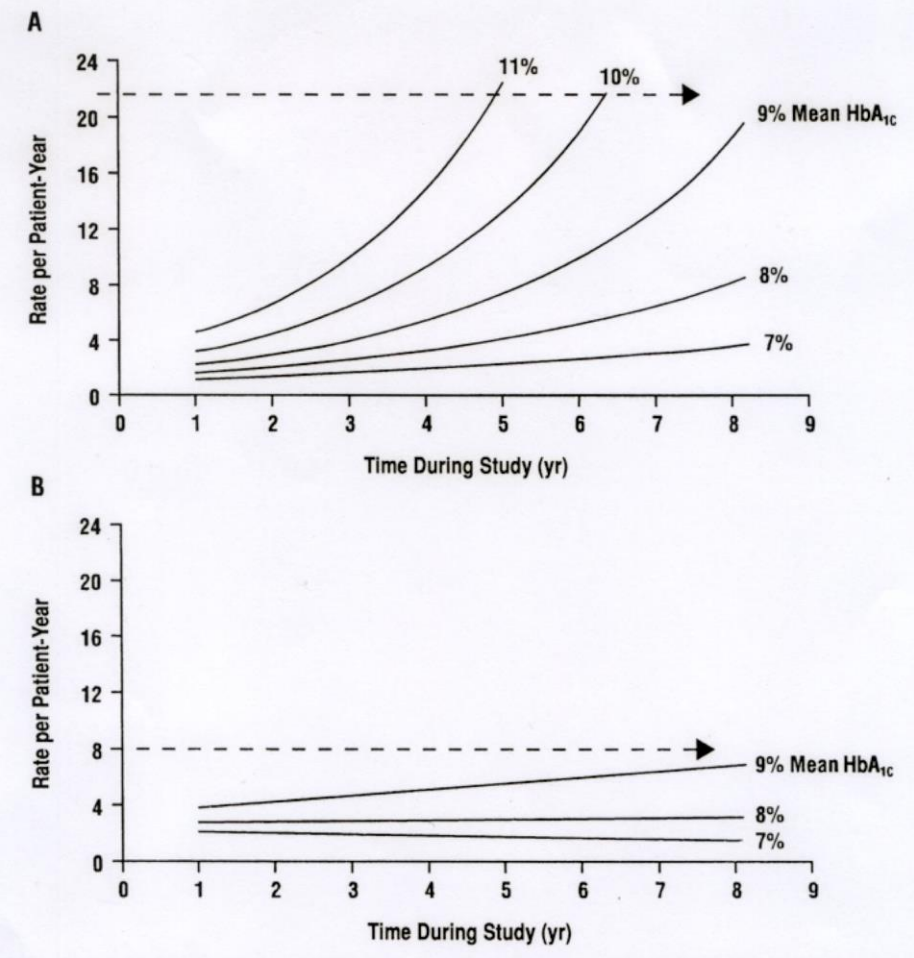
Why We Do It

Better Control Reduces Complications



1. DCCT Research Group, *Ophthalmology.* 1995;102:647-661
2. DCCT Research Group, *Kidney Int.* 1995;47:1703-1720
3. DCCT Research Group, *Ann Intern Med.* 1995;122:561-568.

Pumps Or MDI Are Better Despite A1c



The DCCT conventional group (top) was 22 times more likely to get retinopathy at an A1c of 9%.

The intensive group **at the same A1c** was only 8 times as likely to get retinopathy.

The reduced risk may result from less glucose variability seen with pumps and MDI.

Irl Hirsch: Amer J Med 118 (5A): 21S-26S, 2005

Impact Of Glucose Variability

from Irl Hirsch, MD

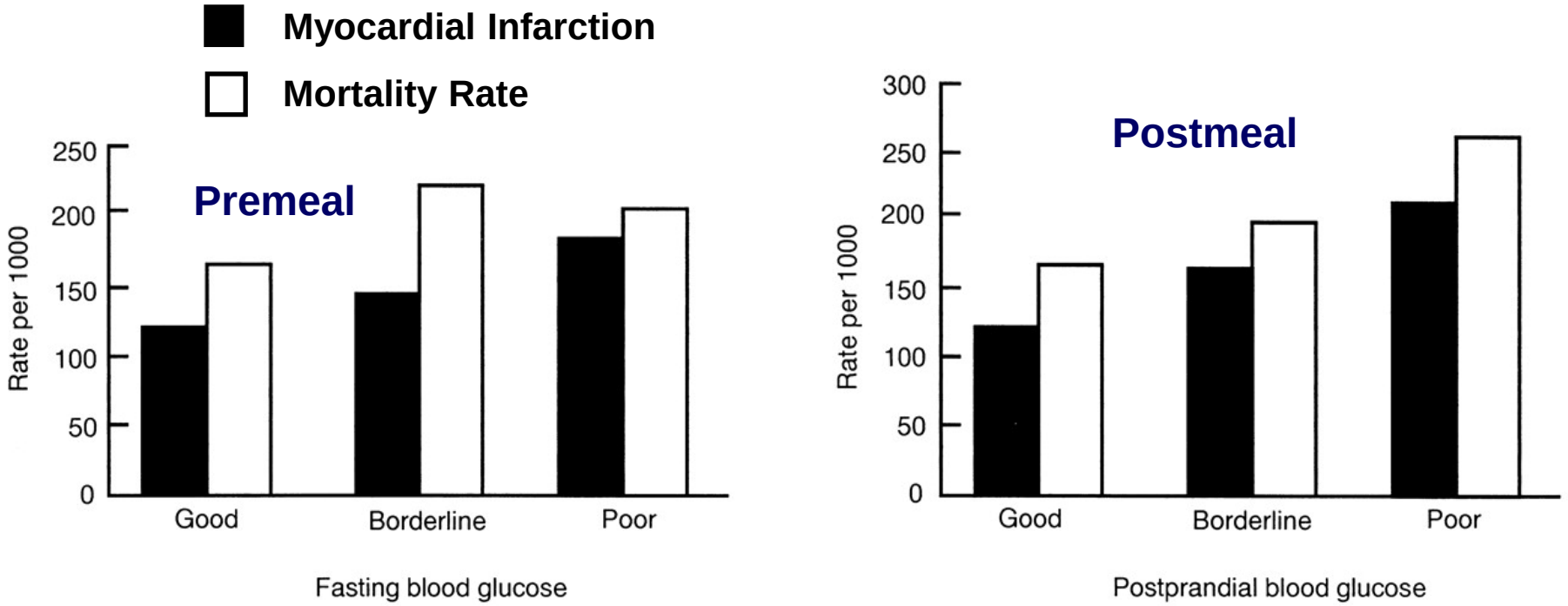
Cell death is about 2.5 times as likely in human umbilical vein endothelial cell cultures after 14 days when glucose varies between 90 and 360 mg/dl compared to cells kept at 360 mg/dl. [1]

Activation of PKC-beta after 14 days is about 80% higher when glucose varies between 90 and 360 mg/dl compared to cells kept at 360 mg/dl. [2]

1. Amer J Physiol Endocrinol Metab 281: E924-E930, 2001
2. Diabetes 52: 2795, 2003

CVD And Mortality In Relation To BG

Heart attacks and death are more closely linked to postmeal blood sugars. Glucose variability may play a role.



1139 diet-controlled subjects, 30-55 yo at diagnosis. During 11 yr followup, 112 (15.2%) suffered from myocardial infarction, 197 (19.82%) of 994 had died. Odds ratio for all-cause mortality for males at the age of 36-45 years was 5.1 and for females 7.0

Haffner Endocrine Reviews 19 (5:583-592) 1998

Pumps Have Come A Long Way

Pump & CGM SYSTEMS

Medtronic 630 with Guardian Sensor
Ages 14 & up

Tandem X2 with G6
Ages 6 & up

Medtronic 770 with Guardian Sensor
Ages 2 & up

Dexcom G6™
Ages 2 & up

Medtronic Minimed® 770G

SMARTGUARD™ TECHNOLOGY

- Similar to previous 670G Hybrid Artificial Pancreas
- Adjust insulin delivery based on sensor glucose (SG) values, with suspend delivery of insulin when SG falls below or is predicted to fall below pre-defined threshold. Manual Mode & Automode.
- Works with the GuardianLink3 transmitter and Guardian Sensor (3)- 7 day sensor, with Bluetooth capability.
- Minimed® Mobile App: see device data on phone and receive alerts when glucose is going high or low; remote uploading to Carelink.
- Carelink ™ Connect App: securely share data with up to 5 people.
- Enabled for future software upgrades: Medtronic offers an upgrade at no charge through December 2021.
- Accuchek Guide-Link Meter
- Approved for ages 2 and up

*** Do not use the SmartGuard™ Auto Mode for people who require less than eight units or more than 250 units of total daily insulin per day.**

Reference: https://www.medtronicdiabetes.com/important-safety-information#minimed-770g
https://www.medtronicdiabetes.com/products/minimed-770g-insulin-pump-system

MEDTRONIC 770G COMPONENTS

CONTINUOUS GLUCOSE MONITOR (CGM)

Measures glucose levels every five minutes and sends readings automatically to the pump.

SMARTPHONE APP

Displays your current glucose level, plus see trends over time on your phone.

INSULIN PUMP

Delivers insulin and communicates with other system components to calculate insulin adjustments.

INFUSION SET

Allows for continuous and discreet delivery of insulin through a thin, flexible tube.

ACCU-CHEK® GUIDE LINK BLOOD GLUCOSE METER

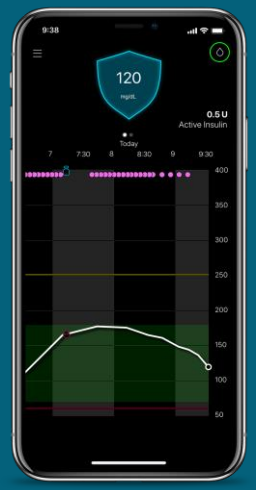
Accurate test results are sent wirelessly to the pump for quick sensor calibrations.

Smartphone apps

AVAILABLE FOR iOS AND ANDROID™

MINIMED™ MOBILE APP
For the pump patient

1. Alert and alarm notifications
2. Insulin delivery information
3. Sensor glucose data
4. 24-hour Time in Range statistics
5. Sync to CareLink™ feature

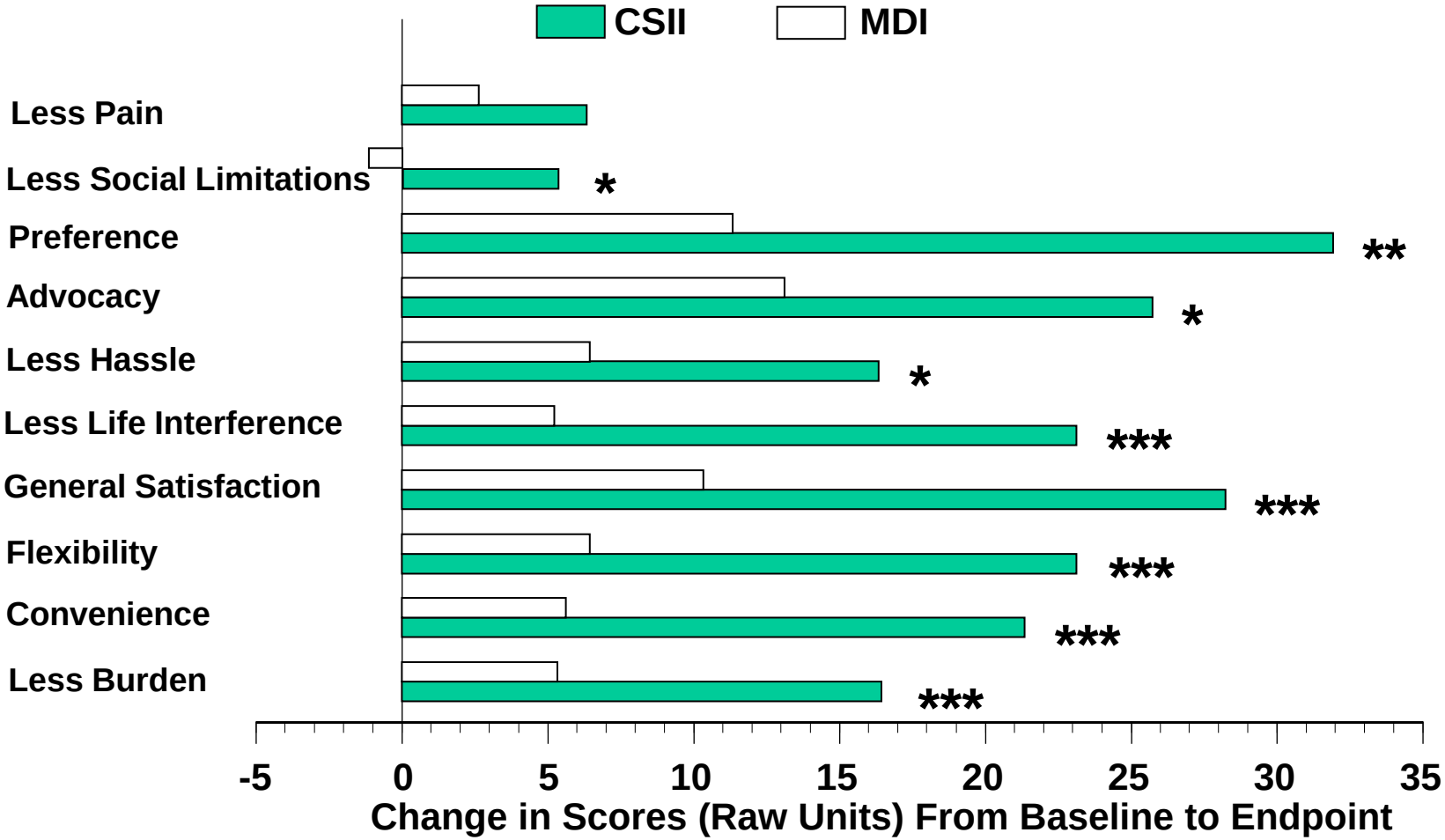


CARELINK™ CONNECT APP
For care partners

1. Alert and alarm notifications
2. Insulin delivery information
3. Sensor glucose data
4. 24-hour Time in Range statistics
5. History log

Pumps vs MDI in Type 2 DM

People with Type 2 diabetes who have tried both a pump and MDI strongly prefer the pump.



MA Testa et al: *Diabetes*, 2001, 50 (suppl 2):1781

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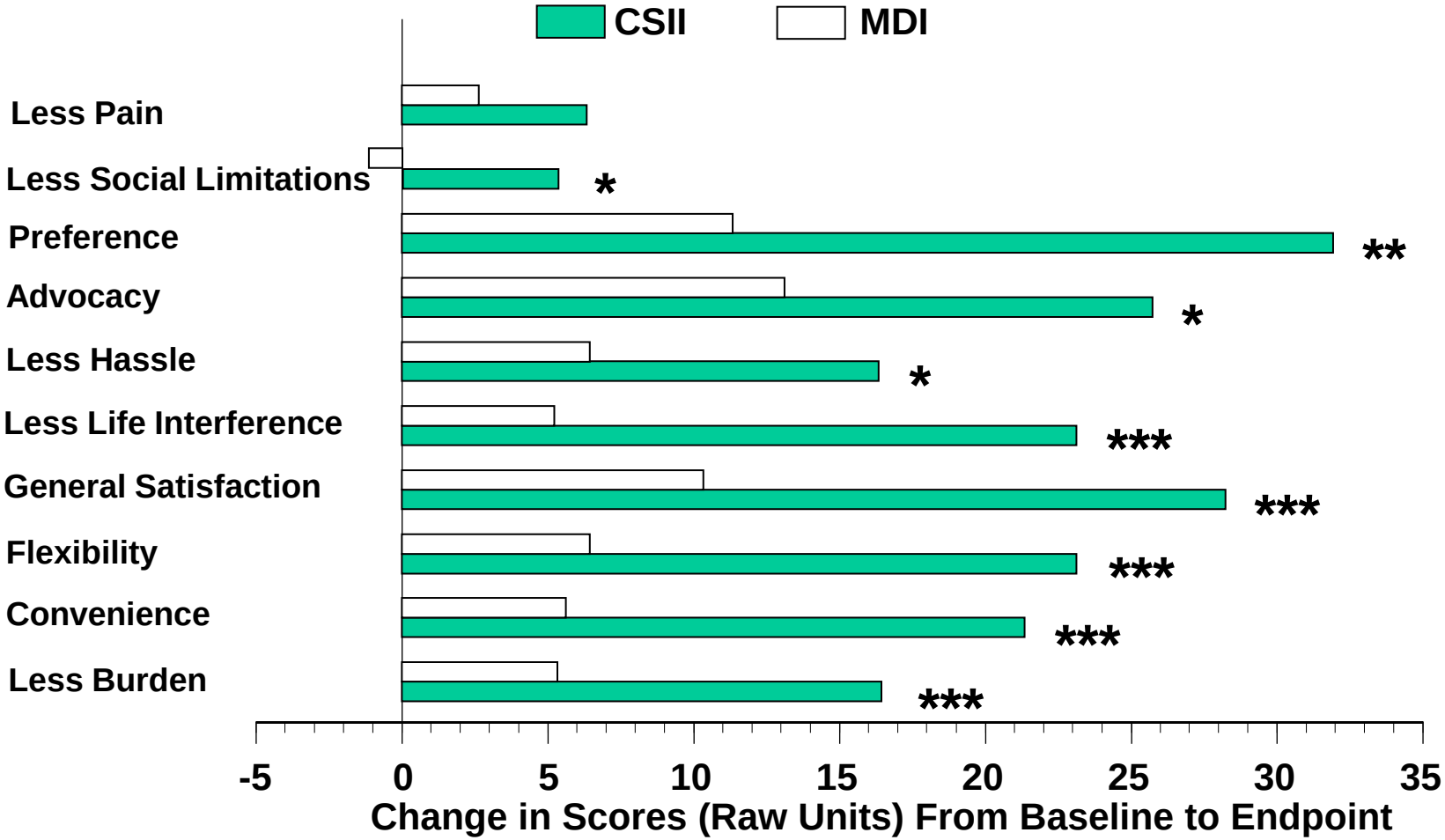
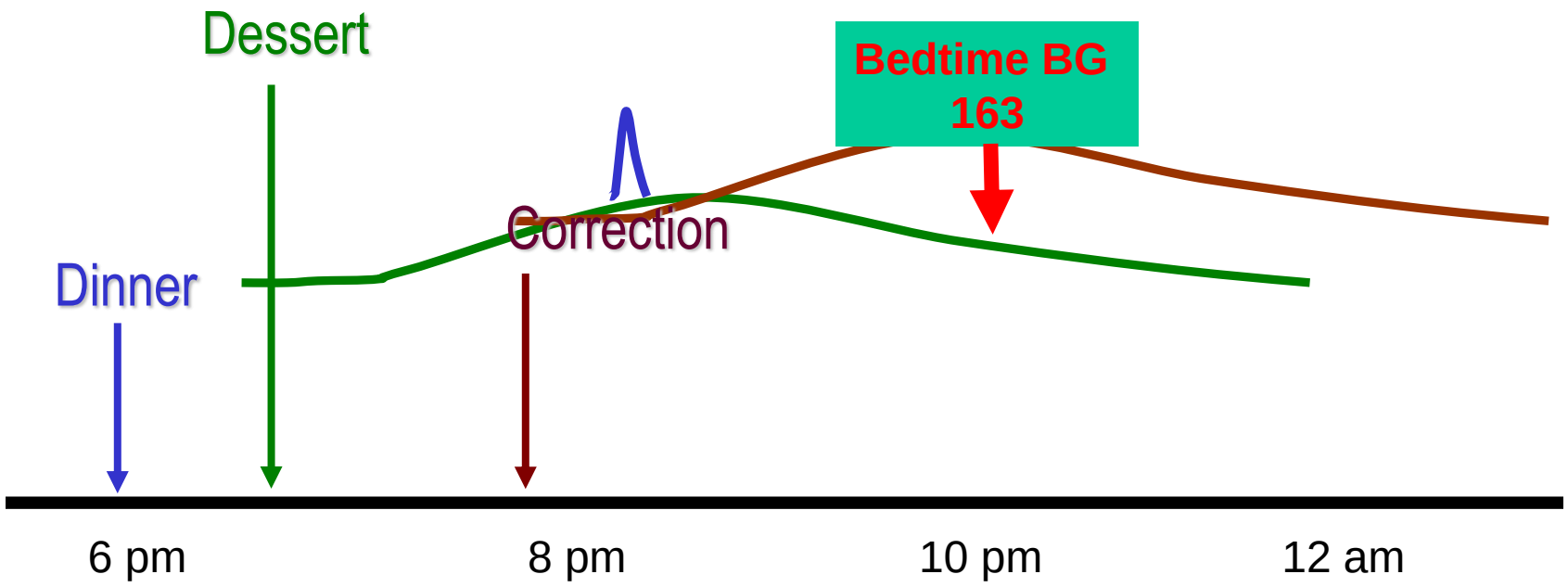


MA Testa et al: *Diabetes*, 2001, 50 (suppl 2):1781

Overlapping Boluses

When several boluses are given in the evening, how much total bolus insulin remains at bedtime?



Basal Rates

- Basal rates that are set correctly should keep your BG relatively stable in the absence of food, exercise or extra insulin
- Basal rates should be evaluated when there is variability in BG readings, change of season, significant weight changes or change in physical status

Initial Calculations for CSII

TDD: total daily dose

METHOD 1

Pre-pump TDD

Pre-Pump TDD x 0.75

METHOD 2

Patient Weight

Wt (kg) x 0.50

STARTING Pump TDD

Average method 1 & 2

BASAL RATE

Pump TDD x 0.5 / 24

- Start with 1 basal rate, adjust according to glucose trends over 2-3 days
- Adjust to maintain stability in fasting state (between meals & sleep)
- Add additional basals according to diurnal variation (dawn phenomenon)

CARB RATIO

450 / Pump TDD

- Adjust based on low-fat meals with known carbohydrate content
- Acceptable 2-h post-prandial rise is ~60mg/dL above pre-prandial BG
- Adjust carb ratio in 10%-20% increments based on post-prandial BG

CORRECTION RATIO

1700 / Pump TDD

- Sensitivity Factor is correct if BG is within 30 mg/dL of target range within 2 hours after correction
- Make adjustments in 10%-20% increments if 2-hr post-correction BGs are consistently above or below target

Hypoglycemia patients – start at lower value of method 1 & 2
Hyperglycemic, elevated A1C or pregnant – start at higher value of method 1 & 2

Consensus Statement by AACE/ACE insulin pump management task force. Endocr Pract. 2014 May; 20(5):463-89.

How Does Control-IQ Technology Work?

Control-IQ™ technology is designed to help increase time in range (70—180 mg/dL)* using Dexcom G6 continuous glucose monitoring (CGM) values to predict glucose levels 30 minutes ahead and adjust insulin delivery accordingly, including delivery of automatic correction boluses (up to one per hour).

		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

*As measured by CGM.

Pt CB

Glucose (BG)

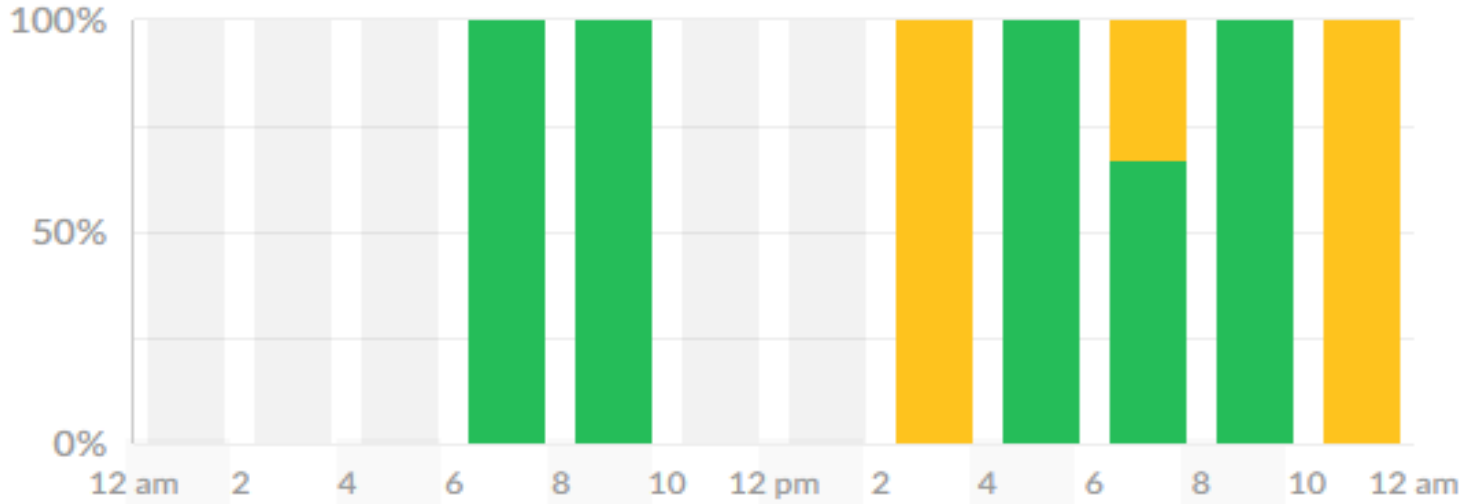
0%	**Very High** > 250 mg/dL	
25%	**High** 181-250 mg/dL	
75%	**Target Range** 70-180 mg/dL	
0%	**Low** 54-69 mg/dL	
0%	**Very Low** < 54 mg/dL	

Average	160 mg/dL
SD	31 mg/dL
Median	158 mg/dL
Highest	215 mg/dL
Lowest	110 mg/dL

Readings/Day	**0.9**

Show Readings (by meal)

Bi-hourly | Time of Day | Day of Week



Insulin

84%
51.4 units
Basal/Day

16%
9.6 units
Bolus/Day

Daily Dose	61 units
Overrides (%)	0% (0 boluses)
# Bolus/Day	1.9

Diet

33.1 g
Carbs/Day

1.6
Entries/Day

Fitness

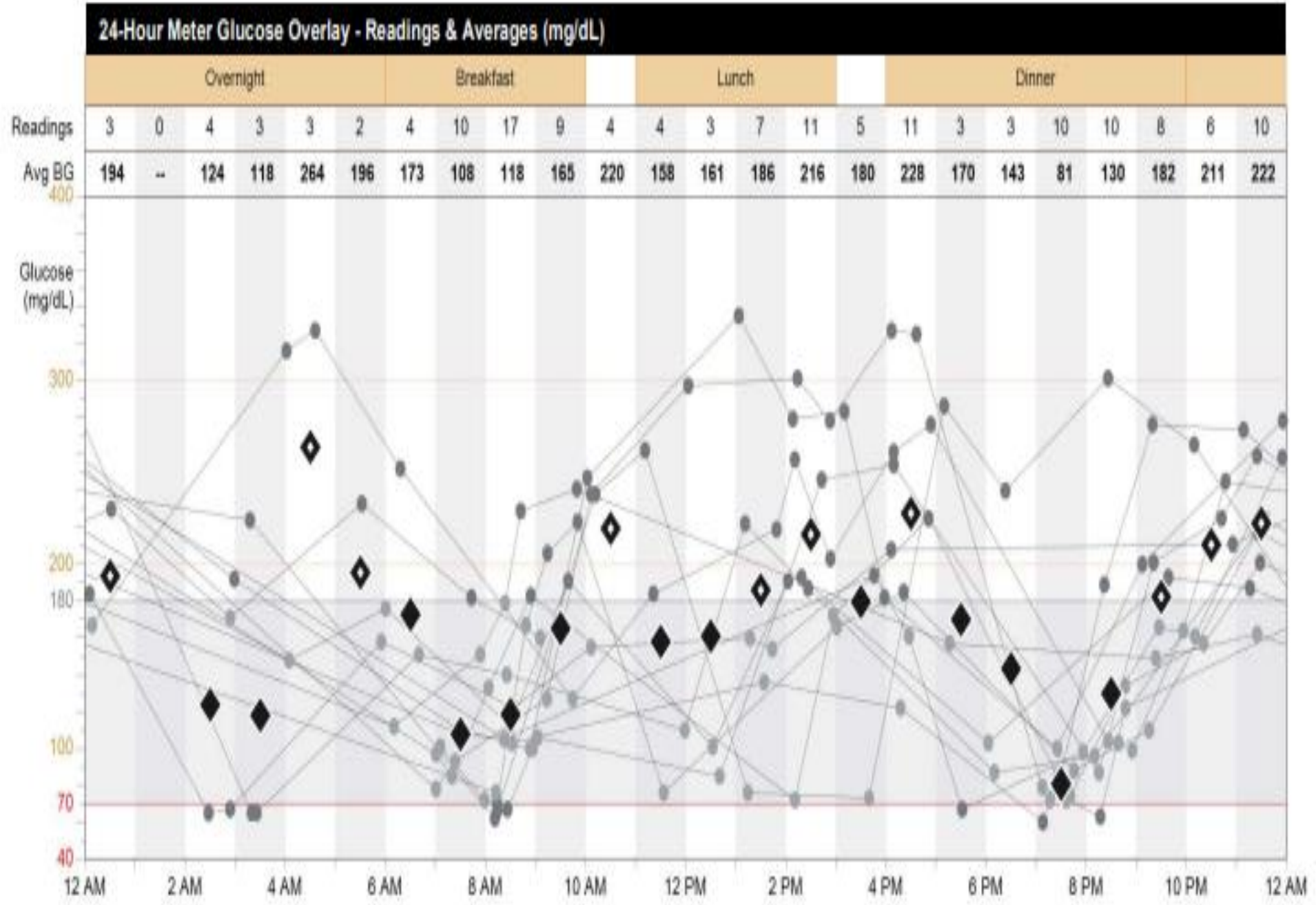
-
Steps/Day

History

Filter Reset

Thursday, September 30, 2021

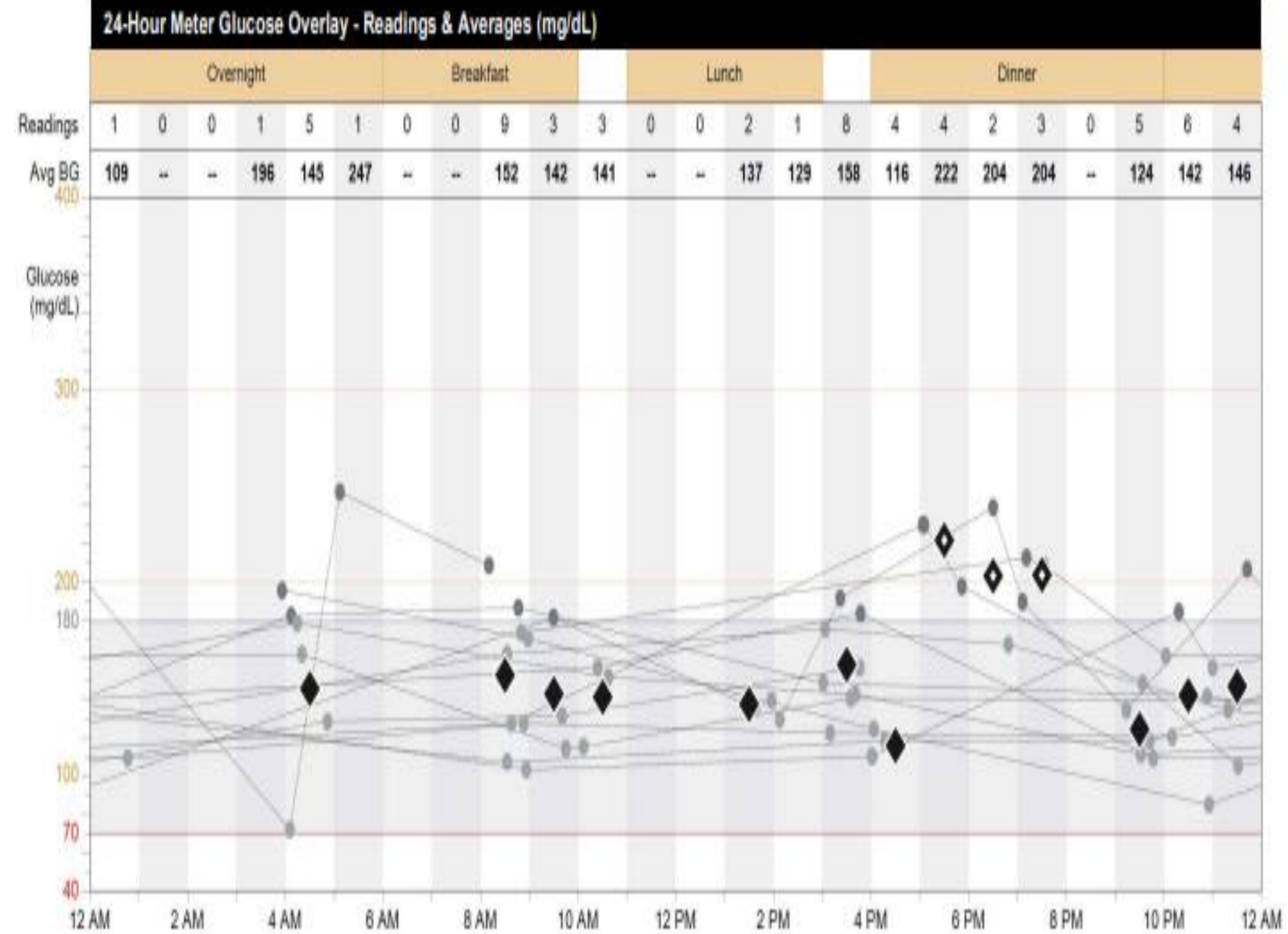
Bolus



Statistics	06-23 - 07-06	
Avg BG (mg/dL)	166 ± 73	
BG Readings	150	10.7/day
Readings Above Target	64	43%
Readings Below Target	10	7%

Avg Daily Carbs (g)	127 ± 49	
Carbs/Bolus Insulin (g/U)	4.2	

Avg Total Daily Insulin (U)	100.8 ± 16.2	
Avg Daily Basal (U)	69.0	68%
Avg Daily Bolus (U)	31.8	32%



Statistics	03-20 - 04-02	
Avg BG (mg/dL)	155 ± 41	
BG Readings	62	4.4/day
Readings Above Target	18	29%
Readings Below Target	--	0%

Avg Daily Carbs (g)	*103* ± 38	
Carbs/Bolus Insulin (g/U)	9.2	

Avg Total Daily Insulin (U)	30.6 ± 2.8	
Avg Daily Basal (U)	19.1	62%
Avg Daily Bolus (U)	11.5	38%

AGP Report

March 5, 2020 - March 17, 2020 (13 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

March 5, 2020 - March 17, 2020	13 Days
% Time CGM is Active	100%

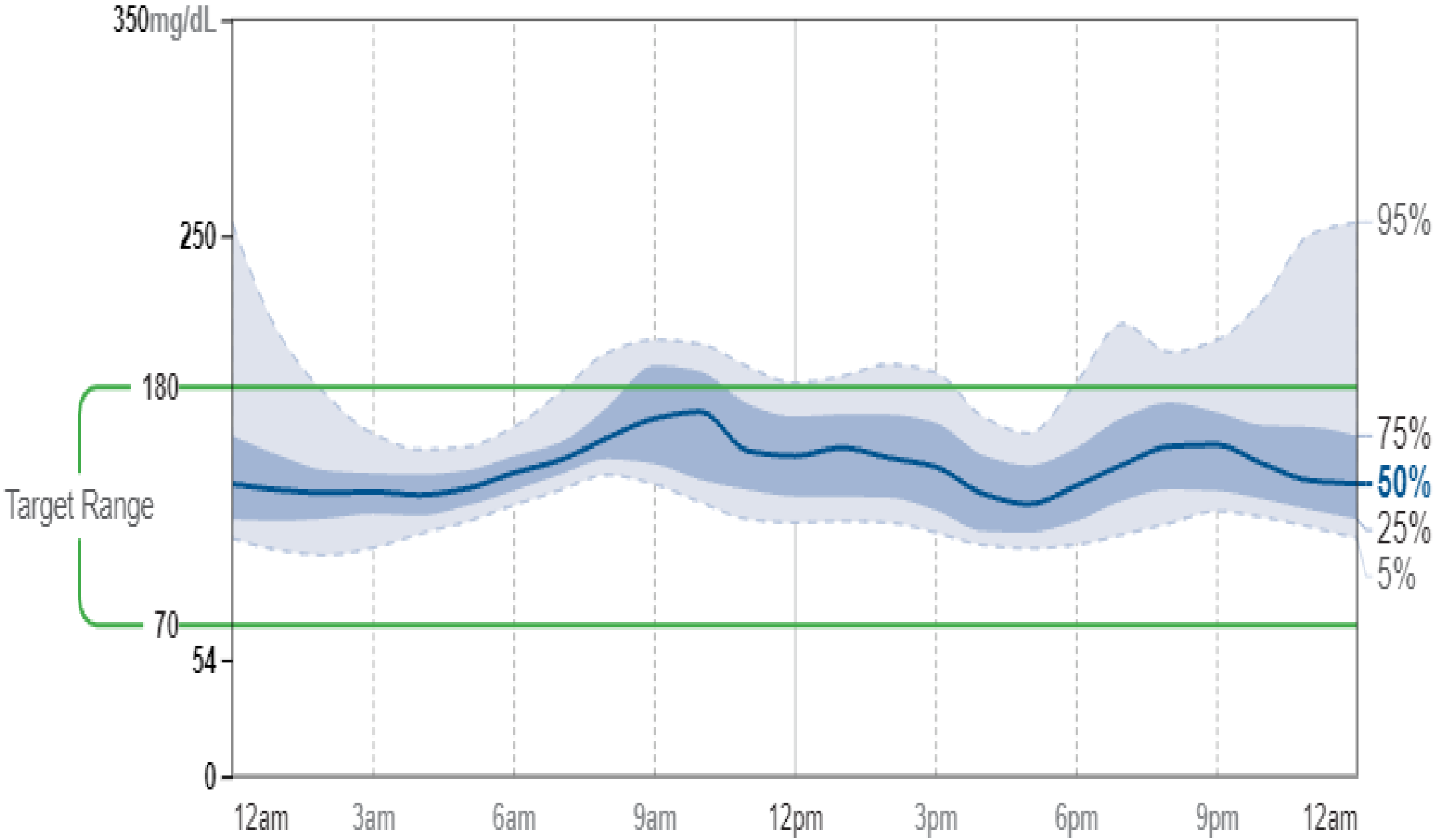
Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges Target Range 70-180 mg/dL	**Targets** % of Readings (Time/Day) Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)
Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.	

Average Glucose	146 mg/dL
Glucose Management Indicator (GMI)	6.8%
Glucose Variability	18.6%

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

TIME IN RANGES

Very High	>250 mg/dL	1%	(14min)
High	181 - 250 mg/dL	10%	(2h 24min)
Target Range	70 - 180 mg/dL	89%	(21h 22min)
Low	54 - 69 mg/dL	0%	(0min)
Very Low	<54 mg/dL	0%	(0min)


350mg/dL
250
180
70
54
0
Target Range
12am
3am
6am
9am
12pm
3pm
6pm
9pm
12am
95%
75%
50%
25%
5%

Omnipod DASH

- **The Dash PDM – Bluetooth enabled PDM (Personal Data Manager) a locked-down, touchscreen, color Android phone**
- **Bluetooth & WiFi system allows for**: data upload to Glooko and smartphone connectivity remote software updates
- **Recent DASH software update allows automatic uploads to Glooko****
- **The Omnipod Display app** allows users to discreetly monitor their pump data on their own smartphone
- **The Omnipod View app** allows up to 12 followers to monitor their loved ones' insulin pump information (this is completely optional).
- *Processed through Pharmacy Benefit.*

To have the automatic uploads you must have a Glooko account, be connected to WiFi and have a Podder Central Account.

Reference: https://www.myomnipod.com/about

Insulet Corporation

Insulet's Omnipod DASH™ System

Received FDA Alternate Controller Enabled (ACE) Classification

(September 2019)

Pumps that meet this FDA qualification have special controls for assuring accuracy, reliability, cybersecurity and clinical relevance of ACE pumps.

What's Coming 2021: OmniPod Horizon(Omnipod 5)

Not FDA Approved

- **Automated insulin delivery system (AID)**
- **Automatically adjust basal insulin delivery based on CGM**
- **Integrate Freestyle Libre 2, G6, and G7 CGMs, first AID system with 2 CGM Partners**
- **Omnipod 5 is also set to bring mobile app control and insulin dosing, eliminating the need to carry a separate Personal Diabetes Manager (PDM) around to control the Omnipod.**

Reference:
https/www.danatech.org/news/diabetesmine-new-diabetes-technology-what-to-expect-in-2021/
https://www.healthline.com/diabetesmine/new-diabetes-technology-coming-in-2021

What's Coming?

Medtronic Minimed 780G

- ***Advanced Hybrid Closed Loop***
- ***Bluetooth connectivity***
- ***Maximize automode***
- ***Automatic correction bolus'***
- **Adjustable target blood glucose level down to 100 mg/dl.**
- **Remote software updating**

Clinical trials completed; hope to have FDA approval by late 2020
Recently approved in Europe.

Source: ADA 2019 Highlights: https://diatribe.org/ada-2019-day-2-highlights#nutrition

t:slim X2™
Insulin Pump

- High definition color screen with touchscreen
- Rechargeable battery, battery life 4-6 days. *If using CGM: 4 days
- 300-unit reservoir, minimum fill 95 units
- Watertight
- New software changes can be uploaded with Tandem Device Updater
- An advanced Bluetooth radio capable of communicating with more than one device at a time and future technologies

- **Basal IQ Approved for ages 6 years & up**
- **Control IQ approved for ages 6 years & up (June 2020)**

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

TslimX2 with Control IQ

- Discontinues basal delivery based on falling CGM values
- Gradually increases basal insulin based on increasing CGM values
- Administers automatic correction boluses once an hour to prevent ongoing hyperglycemia.

Optional Sleep and Exercise Activity Settings

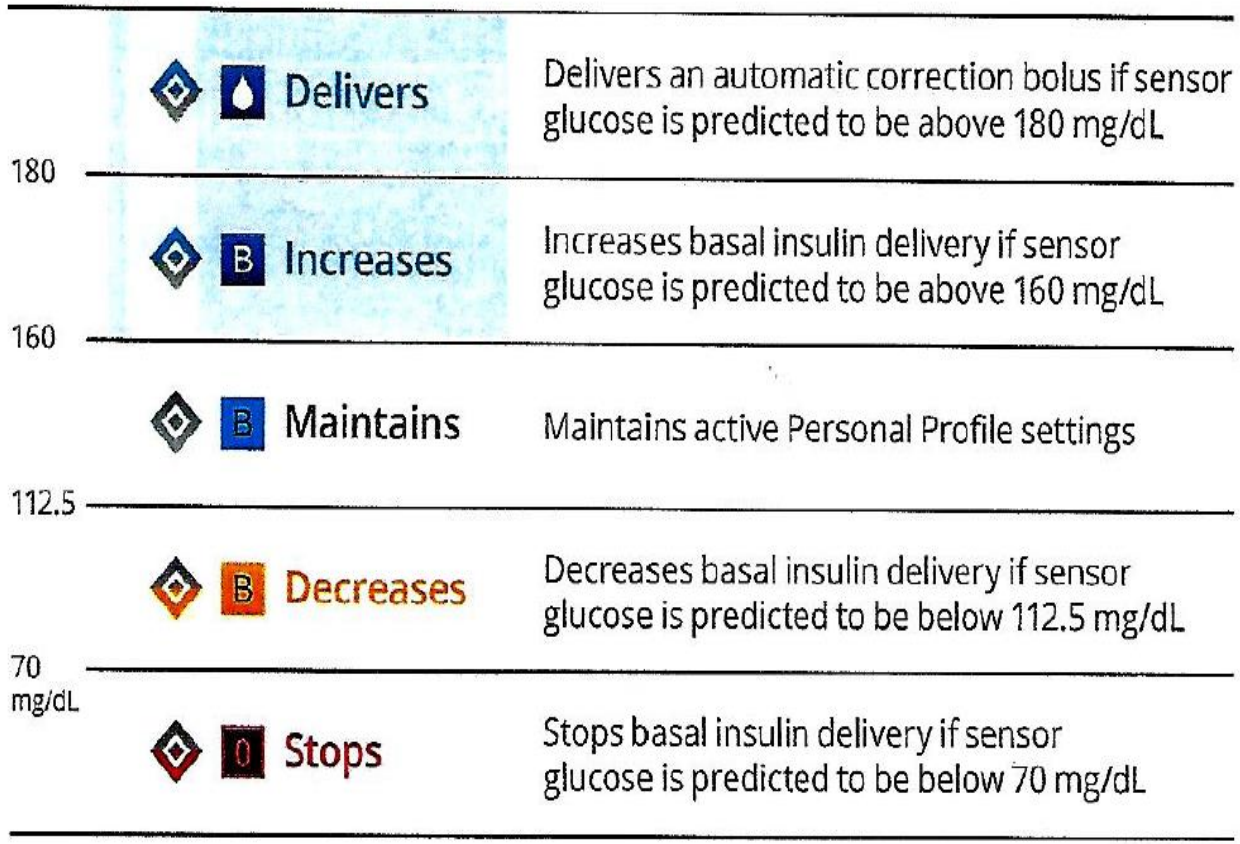
adjust treatment ranges to better match physiologic needs when active or sleeping.

Control IQ targets 110mg/dl. Therefore is not recommended in Pregnancy.
Control IQ is not recommended if an individual uses less than 10 units of insulin per day
Or weight is less than 55lbs or under age 6.

Reference:https://www.tandemdiabetes.com/providers/products/control-iq

How Does Control-IQ Technology Work?

Control-IQ™ technology is designed to help increase time in range (70–180 mg/dL)* using Dexcom G6 continuous glucose monitoring (CGM) values to predict glucose levels 30 minutes ahead and adjust insulin delivery accordingly, including delivery of automatic correction boluses as needed.†



Not FDA Approved

What's coming?

Tandem's mobile bolusing

The company had already filed its expanded mobile app functionality with the FDA at the end of 2020, according to investor updates.

With that added function, the newly designed **t:connect app** — launched in mid-2020 alongside Tandem's Control-IQ system — will allow for remote bolusing via mobile app for the existing t:slim X2 pump platform and beyond.

Reference:
https/www.danatech.org/news/diabetesmine-new-diabetes-technology-what-to-expect-in-2021/
https://www.healthline.com/diabetesmine/new-diabetes-technology-coming-in-2021

What's Coming? Not FDA Approved

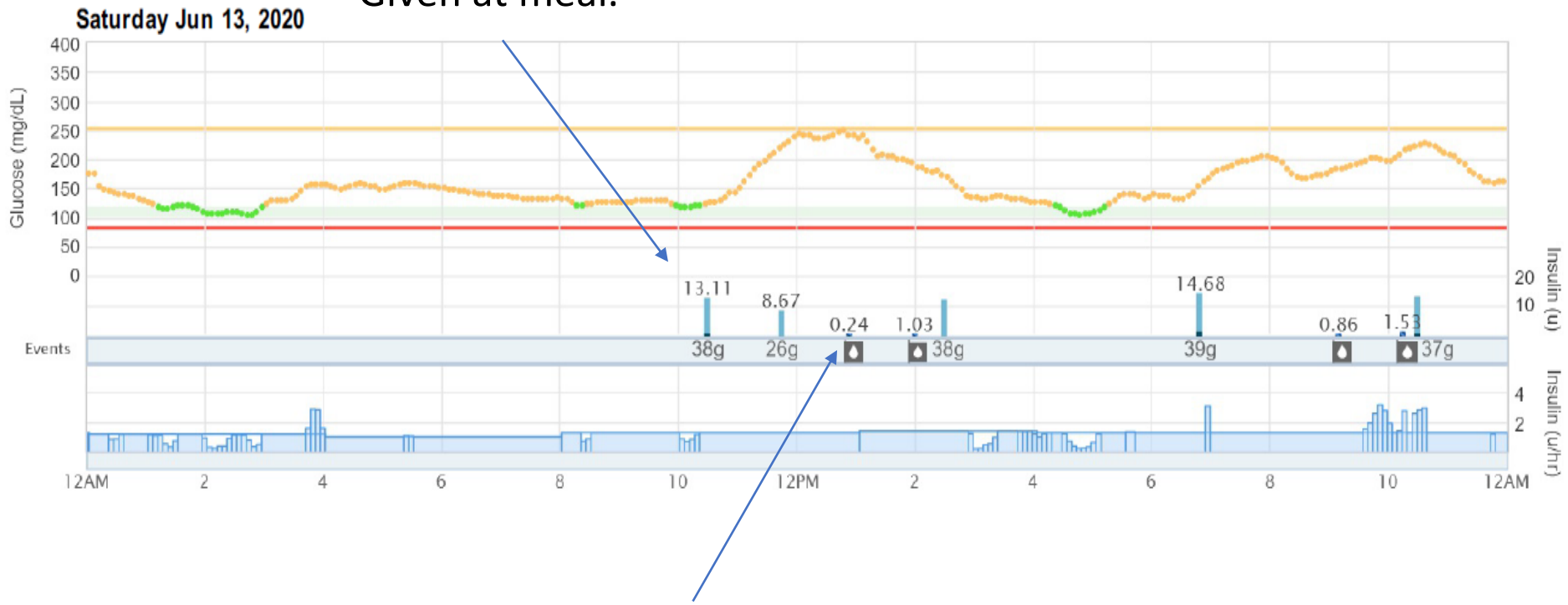
t:sport Insulin "Patch" Pump with Hybrid

- expected to hold 200 units of insulin
- integrate the Control-IQ hybrid closed loop algorithm and receive data from Dexcom CGM
- The t:sport will have an adhesive part, but also the t:slim's trademark t:lock connector "pigtail" insulin tubing that attaches to the infusion set for insulin delivery.
- now expected to be filed with FDA in late 2021, pushing the likely launch to either the end of 2021 or early 2022.

Reference:
https/www.danatech.org/news/diabetesmine-new-diabetes-technology-what-to-expect-in-2021/
https://www.healthline.com/diabetesmine/new-diabetes-technology-coming-in-2021#Smartphone-control-of-devices-

TANDEM DIABETES CARE

Bolus entered correction, with carbs,
Amount of insulin displayed shows insulin
Given at meal.



Automatic correction bolus, pump is trying to compensate for highs.

Tandem Additional Developments

t:connect Mobile App

- Allowing users to view pump status and alerts on phone.
- Wirelessly upload pump data to Tandem t:connect web based diabetes data application.

DOB: Jun 18, 1949 Diabetes: Type 2 Dec 25, 2020 - Jan 7, 2021 (14 day

Glucose (BG)

	All Readings 70 - 180 mg/dL	Before Meal 70 - 130 mg/dL	After Meal 70 - 180 mg/dL
	4% / 96% / 0%	0% / 0% / 0%	0% / 0% / 0%
Average	132 mg/dL	- mg/dL	- mg/dL
Median	132 mg/dL	- mg/dL	- mg/dL
SD	17 mg/dL	- mg/dL	- mg/dL
Readings/Day	1.9	-	-
Highest	188 mg/dL	- mg/dL	- mg/dL
Lowest	110 mg/dL	- mg/dL	- mg/dL

Bi-Hourly

	12 am	2	4	6	8	10	12 pm	2	4	6	8	10	12 am
Readings	-	-	-	6	2	5	2	2	1	4	2	2	
Average (mg/dL)	-	-	-	138	119	132	140	123	133	116	127	160	
SD (mg/dL)	-	-	-	7	8	15	7	6	0	6	20	40	

Insulin

Daily Dose	55.7 units
Overrides (%)	0% (0 boluses)
# Bolus/Day	2.9

Diet

Carbs/Day	32.9 g
Entries/Day	2

Fitness

No fitness tracker connected

Comments

Report Printed on Feb 12, 2021

Dashboard | Thursday Feb 04, 2021 - Wednesday Feb 10, 2021

Highest Blood Glucose
257

Average Blood Glucose
181

Lowest Blood Glucose
134

Blood Glucose Summary

Above Target	> 120 mg/dL	**100**%	**4** times
Target Range	100 - 120 mg/dL	**0**%	**0** times
Below Target	< 100 mg/dL	**0**%	**0** times

Highest CGM Reading
360

Average CGM Reading
147

Lowest CGM Reading
43

Control-IQ™ Technology

Average Reading 148 mg/dL

Time in Use	**81**%	**5** d **16** hr.
Control-IQ Set to Off	**0**%	**0** min.
CGM Inactive[1]	**16**%	**1** d **2** hrs.

DOB: Jun 18, 1949 **Diabetes:** Type 2

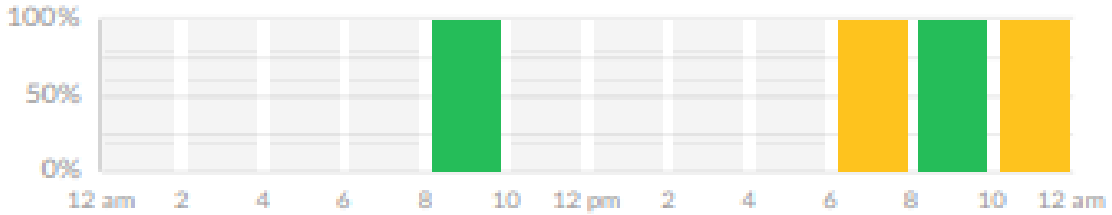
Sep 26, 2021 - Oct 2, 2021 (7 days)

Today: October 4, 2021

Glucose (BG)

	All Readings	Before Meal	After Meal
Very High	0% > 250 mg/dL	0% > 250 mg/dL	0% > 250 mg/dL
High	40% 181-250 mg/dL	0% 131-250 mg/dL	0% 181-250 mg/dL
Target Range	60% 70-180 mg/dL	0% 70-130 mg/dL	0% 70-180 mg/dL
Low	0% 54-69 mg/dL	0% 54-69 mg/dL	0% 54-69 mg/dL
Very Low	0% < 54 mg/dL	0% < 54 mg/dL	0% < 54 mg/dL
Average	167 mg/dL	- mg/dL	- mg/dL
SD	42 mg/dL	- mg/dL	- mg/dL
Readings/Day	0.7	-	-
Median	162 mg/dL	- mg/dL	- mg/dL
Highest	215 mg/dL	- mg/dL	- mg/dL
Lowest	110 mg/dL	- mg/dL	- mg/dL

Bi-Hourly



	12 am	2	4	6	8	10	12 pm	2	4	6	8	10	12 am
Readings	-	-	-	-	1	-	-	-	-	1	2	1	
Average	-	-	-	-	162	-	-	-	-	215	128	200	

Insulin

85% 55.7 units Basal/Day

15% 9.9 units Bolus/Day

Daily Dose	65.6 units
Overrides (%)	0% (0 boluses)
# Bolus/Day	1.7

Diet

Carbs/Day	37.8 g
Entries/Day	1.8

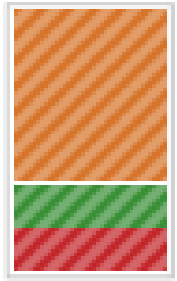
Fitness

No fitness tracker connected

Comments

Time in Range

Above Target	68%	> 120 mg/dL
Target Range	15%	100 - 120 mg/dL
Below Target	16%	< 100 mg/dL



Number of Days
CGM in Use

5.9 days

Pump Inactive[2]	3%	5 hrs. 29 min.

Avg. Sleep & Exercise

Daily Sleep	8 hrs. 35 min.
Weekly Exercise Events	0 times

Average Daily Insulin Summary

Basal	58%	26.92 u/day	
Food Bolus	25%	11.75 u/day	
Correction Bolus	4%	1.78 u/day	
Control-IQ Auto Bolus	13%	6.11 u/day	

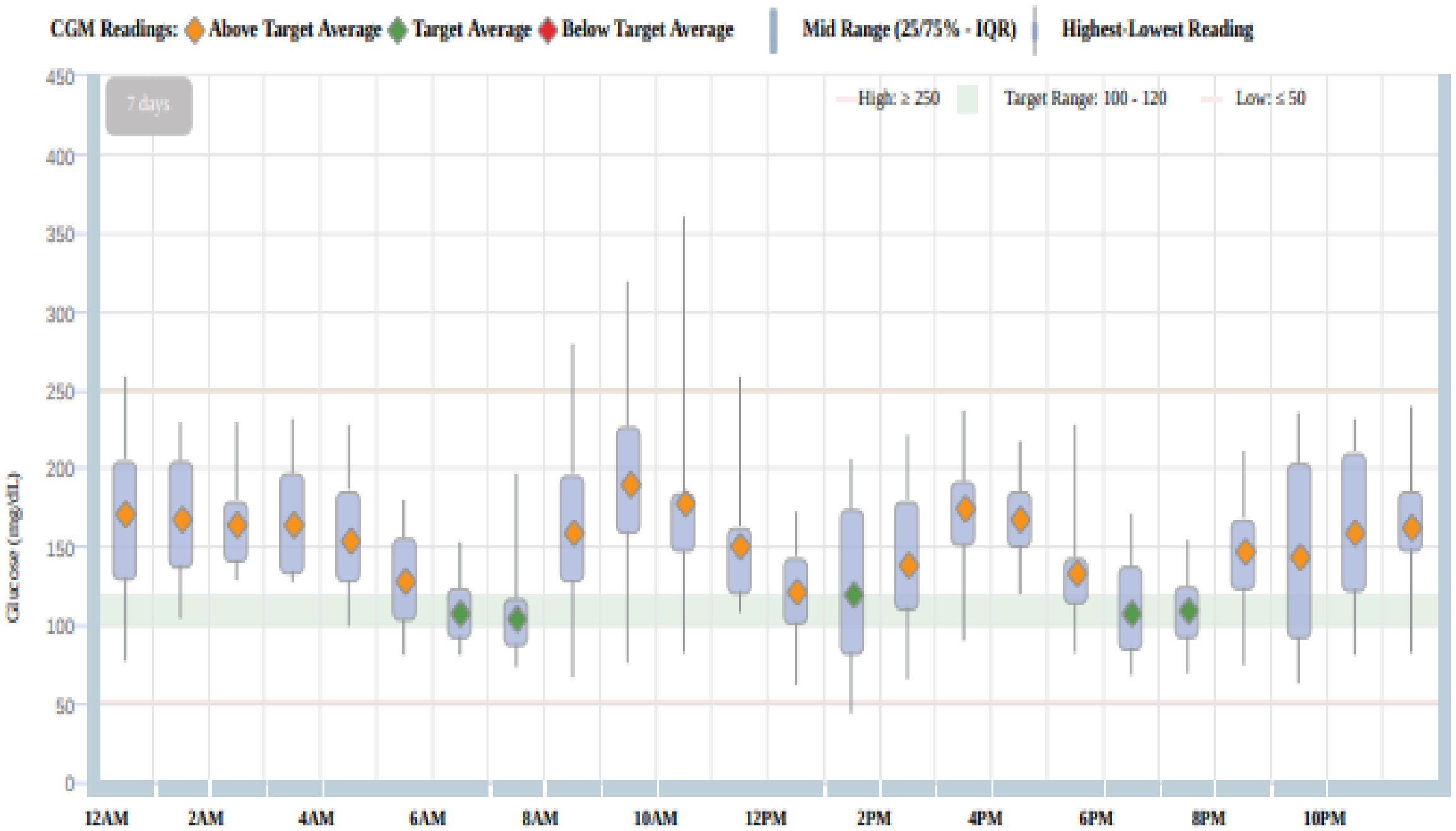
Average Total Daily Dose **46.57** units / day

Average BG Tests **0.57** times / day

Average CGM Readings **243.43** times / day

	Cartridge	Tubing	Site/Cannula
Avg. Change Frequency	Every 3.00 days	Every 3.00 days	Every 3.00 days
Avg. Fill Amount	120.00 units	11.82 units	0.50 units

CGM Hourly | Thursday Feb 04, 2021 - Wednesday Feb 10, 2021



Device Settings

Work Profile

Active at the time of upload

Start Time	Basal Rate	Correction Factor	Carb Ratio	Target BG
Midnight	1.200 u/hr	1u:30 mg/dL	1u:6.0 g	100 mg/dL
3:00 AM	1.300 u/hr	1u:30 mg/dL	1u:6.0 g	100 mg/dL
9:00 AM	1.000 u/hr	1u:30 mg/dL	1u:9.0 g	100 mg/dL
4:00 PM	1.000 u/hr	1u:30 mg/dL	1u:9.0 g	100 mg/dL
8:00 PM	1.200 u/hr	1u:30 mg/dL	1u:9.0 g	100 mg/dL
Calculated Total Daily Basal	27.2 units			

Duration of Insulin: 5:00 hours | **Carbohydrates:** On | **Max Bolus:** 15 units

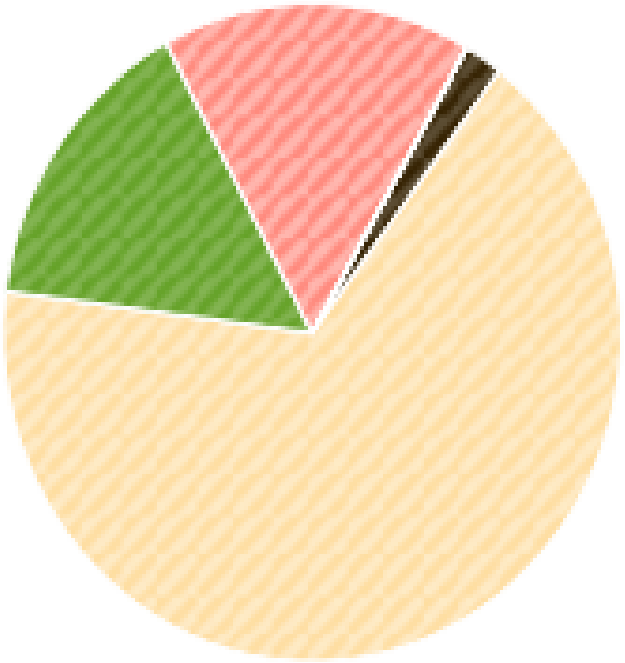
Settings

Alerts	
Alert: Auto-Off	On 12 hrs
Alert: Low Insulin	20 u
Reminders	
Low BG	Off
High BG	Off
Site Change Reminder	On 3 days 2:00 PM
Missed Meal Bolus: Reminder 1	-
Missed Meal Bolus: Reminder 2	-
Missed Meal Bolus: Reminder 3	-
Missed Meal Bolus: Reminder 4	-
After Bolus BG	Off

Pump Settings	
Quick Bolus	Off
Screen Timeout	On 120 sec
Feature Lock	Off
Pump Volume: Button	Low
Pump Volume: Quick Bolus	High
Pump Volume: Bolus	High
Pump Volume: Reminders	Low
Pump Volume: Alerts	Low
Pump Volume: Alarms	Low

Activity Summary | Thursday Feb 04, 2021 - Wednesday Feb 10, 2021

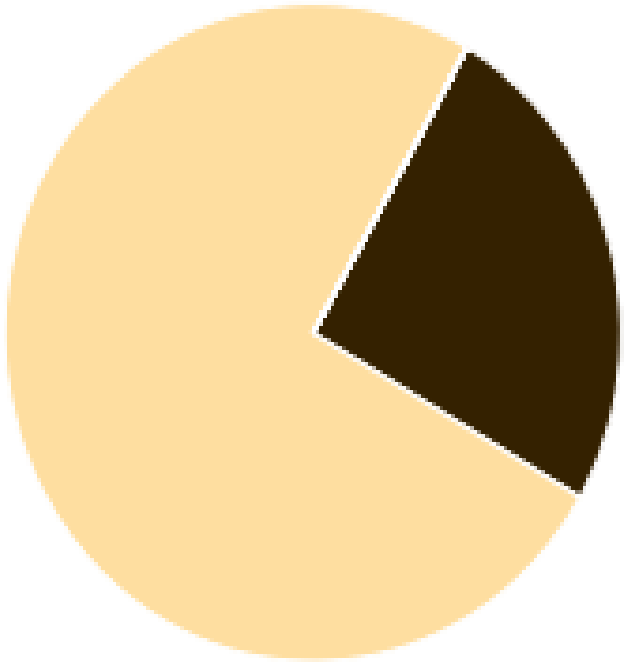
CGM Summary



- High (>=250 mg/dL)
  2% **35** readings
- Above Target (121-249 mg/dL)
  66% **1128** readings
- Within Target (100-120 mg/dL)
  15% **263** readings
- Below Target (51-99 mg/dL)
  16% **273** readings
- Low (<=50 mg/dL)
  0% **5** readings

Average CGM	**147** mg/dL
Standard Deviation	**46.8** mg/dL

Blood Glucose Summary



- High (>=250 mg/dL)
  25% **1** readings
- Above Target (121-249 mg/dL)
  75% **3** readings
- Within Target (100-120 mg/dL)
  0% **0** readings
- Below Target (51-99 mg/dL)
  0% **0** readings
- Low (<=50 mg/dL)
  0% **0** readings

Average BG	**181** mg/dL
Standard Deviation	**46.3** mg/dL

Insulin Delivery Summary

- Avg. Daily Basal Units
  58% **26.92** units
- Avg. Daily Food Bolus
  25% **11.78** units
- Avg. Daily Correction Bolus
  17% **7.90** units
- Avg. Daily Quick Bolus
  0% **0** units
- Avg. Daily Override Bolus
  0% **0** units

Average Total Daily Dose	**46.57** units/day
Average Daily Carbs	**103** grams/day

Bolus Usage Summary

- Food Only Boluses
  55% **11** boluses
- Correction + Food Boluses
  45% **9** boluses
- Correction Boluses
  0% **0** boluses
- Quick Boluses
  0% **0** boluses
- Overridden Boluses
  0% **0** boluses

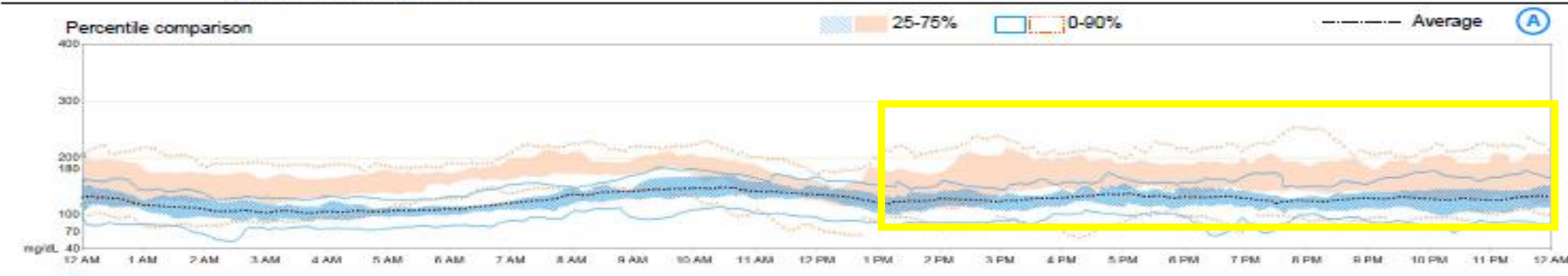
Average Boluses	**7.57** /day
Stopped Boluses	**1.00** boluses

Pt RM

Medtronic

Ⓐ 09-05-2020 - 10-04-2020 (30 Days)
Ⓑ 06-07-2020 - 07-06-2020 (30 Days)

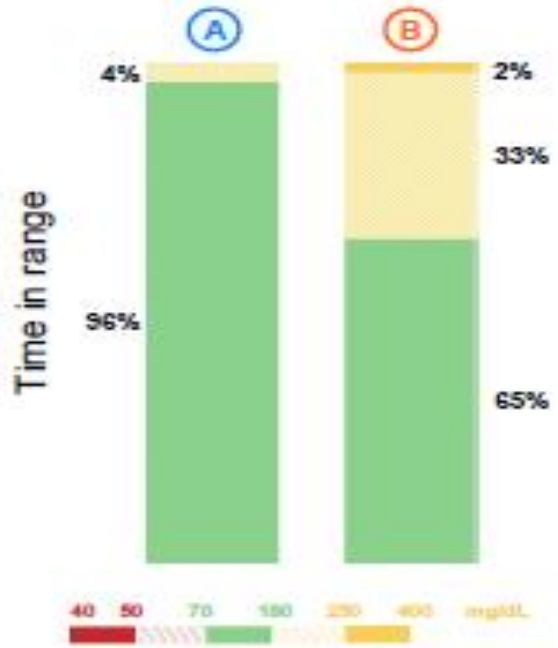
Data Sources: MiniMed 630G, MMT-1715 (NG1980773H)



Carb Ratio (g/U)	
Ⓐ	1.6
Ⓑ	1.5

Ⓐ

Hypoglycemic patterns (0)	# Episodes (per day): 0	Hyperglycemic patterns (0)	# Episodes (per day): 0.3
None		None	



Statistics	Ⓐ	Ⓑ
Sensor Wear (per week)	52% (3d 16h)	64% (4d 12h)
Average SG ± SD	126 ± 27 mg/dL	164 ± 40 mg/dL
GMI***	6.3%	7.2%
Coefficient of Variation (%)	21.5%	24.4%
Low / High SG Alerts (per day)	0.3 / 0.0	0.3 / 2.0
Average BG	148 ± 35 mg/dL	178 ± 51 mg/dL
BG / Calibration (per day)	2.7 / 1.6	3.4 / 2.2
Total daily dose (per day)	73.0 units	129.2 units
Bolus amount (per day)	17.7U (24%)	41.7U (32%)
Basal amount (per day)	55.3U (76%)	87.5U (68%)
Set Change	Every 3.2 days	Every 2.1 days
Reservoir Change	Every 3.2 days	Every 2.1 days
Meal (per day)	0.7	1.0
Carbs entered (per day)	15 ± 12 g	27 ± 26 g
Active Insulin time	3:00 hrs	3:00 hrs

*** Glucose Management Indicator

Medtronic

Ⓐ 09-05-2021 - 10-04-2021 (30 Days)
Ⓑ 06-07-2021 - 07-06-2021 (30 Days)

Data Sources: MiniMed 770G, MMT-1880 (NG2543611H)

Percentile comparison

Carb Ratio (g/U)
Ⓐ 1.5
Ⓑ 1.5

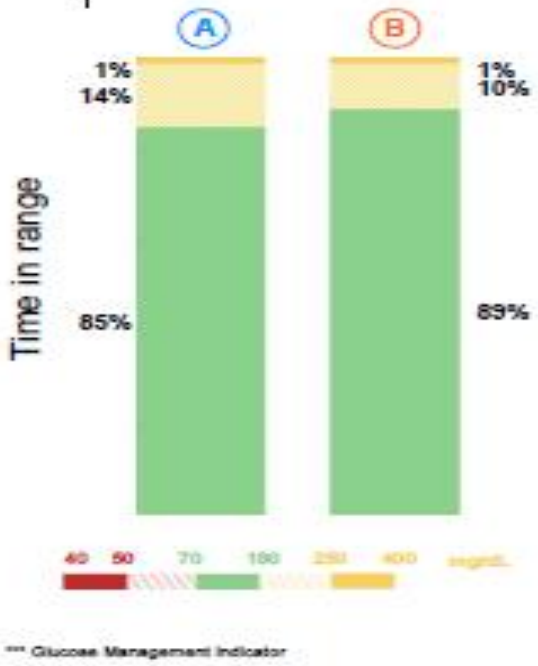
Ⓐ

Hypoglycemic patterns (0) # Episodes (per day): 0

None

Hyperglycemic patterns (1) # Episodes (per day): 1.0

1 1:00 PM - 1:59 PM (5 occurrences)



*** Glucose Management Indicator

Auto Mode Exits	Ⓐ	Ⓑ
No Calibration	0	0
High SG Auto Mode Exit	0	0
Auto Mode max delivery	• 1	7 • • • • • +
Auto Mode min delivery	0	0
BG required for Auto Mode	0	0
Sensor Algorithm Underread	0	1 •
Sensor Updating	0	0
No SG values	0	0
Sensor Expired	0	0
Auto Mode disabled by user	• • • • 4	3 • • •
Alarms	0	0
Pump Suspend by user	0	0
Auto Mode Warm Up	0	0
Unidentified	0	0

Statistics	Ⓐ	Ⓑ
Auto Mode (per week)	60% (4d 05h)	62% (4d 07h)
Manual Mode (per week)	40% (2d 19h)	38% (2d 17h)
Sensor Wear (per week)	59% (4d 02h)	63% (4d 09h)
Average SG ± SD	150 ± 29 mg/dL	147 ± 29 mg/dL
GMI***	6.9%	6.8%
Coefficient of Variation (%)	19.5%	19.6%
Low / High SG Alerts (per day)	0.1 / 0.2	0.3 / 0.2
Average BG	171 ± 45 mg/dL	159 ± 38 mg/dL
BG / Calibration (per day)	2.6 / 2.1	2.5 / 2.1
Total daily dose (per day)	103.5 units	82.7 units
Bolus amount (per day)	35.0U (34%)	22.0U (27%)
Auto Basal / Basal amount (per day)	68.5U (66%)	60.7U (73%)
Set Change	Every 2.5 days	Every 3.5 days
Reservoir Change	Every 2.3 days	Every 3.5 days
Meal (per day)	2.1	1.2
Carbs entered (per day)	41 ± 22 g	26 ± 21 g
Active Insulin time	3:00 hrs	3:00 hrs

This report is compatible with the Ambulatory Glucose Profile calculations used by the International Diabetes Center

Summary

- Advanced diabetes technology holds the promise to be beneficial for all patients with diabetes
- Technologies provide insight in targeting a rational, safe and comprehensive approach to glycemic management
- Patients using advanced technology have been able to improve their time in range, reduce risk of and time spent within hypoglycemia, improve quality of life

THANK YOU!!