

P1752.2 Metabolic Subgroup Meeting

Working Group Sponsored by IEEE Engineering in
Medicine & Biology (EMB) Standards Committee

8 March 2022

Teleconference

Agenda

1. Attendance
2. Review of action items
3. Review of tasks
4. Other business

Review of Action Items

Data elements, definitions, units of measure

- Glucose (mg/dL)
- Time in range (%) [TIR] <http://www.agpreport.org/agp/agpreports>
- Time above range [TAR]
- Time below range [TBR]
- Mean glucose (average) \pm standard deviation

Ambulatory Glucose Profile CGM

AGP Report

Name _____

MRN _____

GLUCOSE STATISTICS AND TARGETS

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

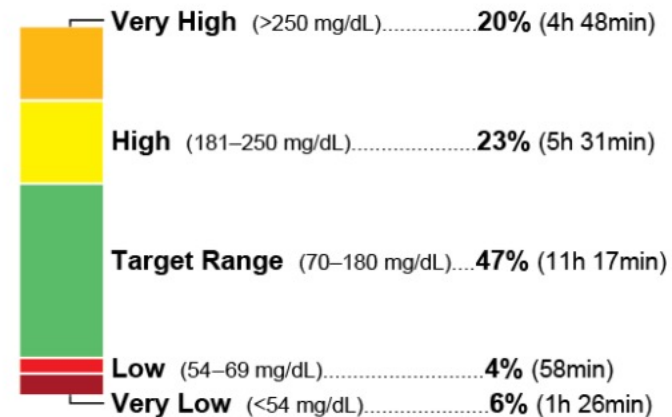
Glucose Ranges	Targets [% of Readings (Time/Day)]
Target Range 70-180 mg/dL.....	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 250 mg/dL	Less than 5% (1h 12min)

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

Average Glucose **173 mg/dL**
Glucose Management Indicator (GMI) **7.6%**
Glucose Variability **49.5%**

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

TIME IN RANGES

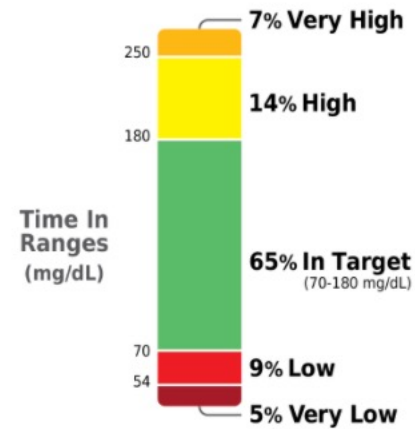


Ambulatory Glucose Profile Self Monitoring BG

capturAGP® Name _____

Glucose Statistics

15 Feb 2018 - 01 Mar 2018	14.5 days
Average Tests per Day	6.4
Average Glucose	135 mg/dL
Glucose Management Indicator (GMI)	6.3%
Coefficient of Variation (CV)	47%
Standard Deviation (SD)	64 mg/dL



Data elements, definitions, units of measure

- Percentage coefficient of variation for glucose ($\%CV = [(SD \text{ of glucose}) / (\text{mean glucose})]$)
- Glucose Management Indicator (GMI)
tells you the approximate A1C level based on the average glucose level from CGM readings for 14 or more days (eA1C \rightarrow GMI)
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6196826/>
- Number of hypo/hyper events

Additional measures

- Average daily carbs (g)
- Mean amplitude of glycemic excursions (MAGE): the arithmetic mean of differences between consecutive peaks and nadirs of differences greater than one SD of mean glycemia
- Mean of daily differences (MODD: the mean of absolute differences between glucose values at corresponding time points of consecutive days)

Additional measures (metadata)

- Sensor usage (%)
- Calibration
- “A number of metrics have been proposed to characterise the accuracy of the CGMs and one, in particular, has emerged as being the most recurrent measure for the sensor accuracy, which is the mean absolute relative difference (MARD). Different studies reported MARD values of 9.5% to 19% for different CGM sensors, which are close to the values reported for glucometers (5.6% and 20.8%).” <https://www.nature.com/articles/s41598-019-56927-5>

Table 6.2

Standardized CGM metrics for clinical care

1. Number of days CGM device is worn (recommend 14 days)	
2. Percentage of time CGM device is active (recommend 70% of data from 14 days)	
3. Mean glucose	
4. Glucose management indicator	
5. Glycemic variability (%CV) target $\leq 36\%$ *	
6. TAR: % of readings and time >250 mg/dL (>13.9 mmol/L)	Level 2 hyperglycemia
7. TAR: % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L)	Level 1 hyperglycemia
8. TIR: % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L)	In range
9. TBR: % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L)	Level 1 hypoglycemia
10. TBR: % of readings and time <54 mg/dL (<3.0 mmol/L)	Level 2 hypoglycemia

CGM, continuous glucose monitoring; CV, coefficient of variation; TAR, time above range; TBR, time below range; TIR, time in range.

* Some studies suggest that lower %CV targets ($<33\%$) provide additional protection against hypoglycemia for those receiving insulin or sulfonylureas. Adapted from Battelino et al. (26).

Glycemic variability indices

Continuous glucose monitoring

Mean (average) \pm standard deviation

J index

Coefficient of variance

Low blood glucose index, high blood glucose index

Average daily risk range

Mean amplitude of glucose excursion

Mean of daily differences

Continuous overall net glycemic action

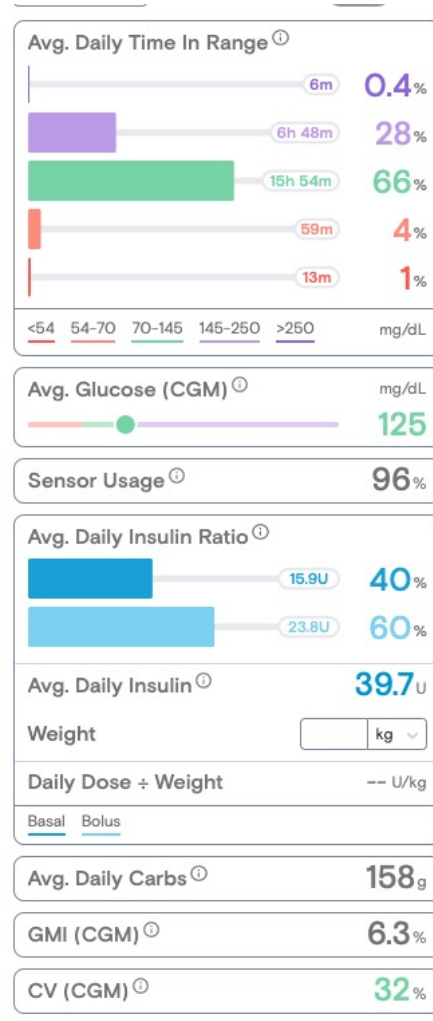
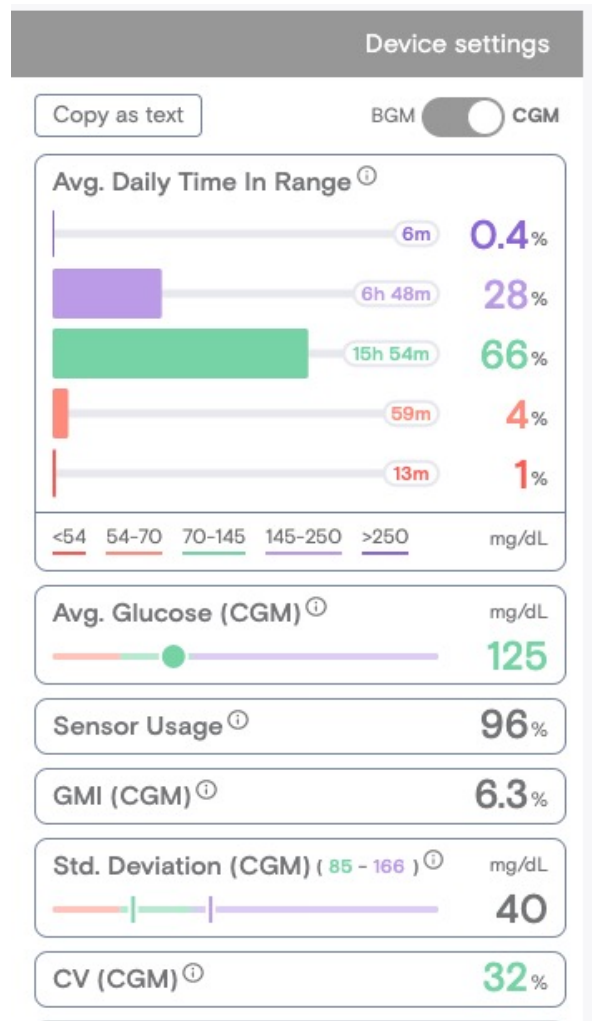
Serum

Glycated albumin

1,5-anhydroglucitol

Glycated albumin/glycosylated hemoglobin ratio

Which measures does Tidepool share with pts/MDs?



Temporal relationships

- Temporal relationship to meal*
- Temporal relationship to sleep*
- Temporal relationship to physical activity
 - e.g., before exercise, after exercise (see related [OMH schema](#))
- Temporal relationship to doses of antihyperglycemic medications
 - May be challenging to implement given the large variety of medications and dosing regimens.

*These elements are present in the Open mHealth [blood glucose schema](#)

Example model instances

- [see AGPsample.json file]

Noninvasive Glucose Monitoring

- ‘Noninvasive’ Glucose Monitoring for Diabetes: Where Is It Now?
<https://www.healthline.com/diabetesmine/non-invasive-diabetes-technology?c=1294427003836#whos-developing-it>
- ‘Noninvasive Glucose Monitoring: In God We Trust—All Others Bring Data’ <https://journals.sagepub.com/doi/full/10.1177/19322968211046326>

Review of Tasks

Reminder: Use Cases

- Use cases
 1. Continuous Glucose Monitoring for type 1 diabetes
 2. Blood Glucose Monitoring for type 2 diabetes on oral treatment
 3. Continuous Glucose Monitoring for type 2 diabetes on insulin
 4. Continuous Glucose Monitoring for response to food intake in prediabetes/Quantified self/biohacker

Summary of Action Items

Next Meeting

Upcoming Meeting

- Metabolic subgroup:
 - Tuesday, April 5 at 8 am Pacific