

Clinical Targets for CGM Data Interpretation

Recommendations From the International Consensus on Time in Range

Adapted with permission from the American Diabetes Association

The International Consensus report has been endorsed by the ADA, AACE, AADE, EASD, ISPAD, JDRF and PES.

While A1C reflects average glucose over the last 2-3 months, it fails to identify glycemic excursions and the magnitude and frequency of intra- and interday glucose variation.¹

Use of continuous glucose monitors (CGMs) provides the data to assess glycemic excursions, glucose variability, and identify patterns of hypo- and hyperglycemia, which can inform therapy decisions.¹

2019 Standardized metrics for CGM data interpretation^{1,2}

| | Target |
|---|-----------------|
| 1. Number of days CGM worn | ≥14 days |
| 2. Percentage of time CGM is active | ≥70% of 14 days |
| 3. Mean glucose | |
| 4. Glucose management indicator (GMI) <ul style="list-style-type: none">• Approximate A1C levels based on average glucose measured using CGM values | |
| 5. Glycemic variability (%CV) <ul style="list-style-type: none">• Glycemic variability is characterized by the amplitude, frequency, and duration of glucose fluctuations• Coefficient of variation (%CV) is used to quantify variability by dividing the standard deviation by the mean | ≤36%* |
| 6. Time above range (TAR) Very High: >250 mg/dL | <5%** |
| 7. Time above range (TAR) High: >180 mg/dL | <25%** |
| 8. Time in range (TIR): 70-180 mg/dL | >70%** |
| 9. Time below range (TBR) Low: <70 mg/dL | <4%** |
| 10. Time below range (TBR) Very Low: <54 mg/dL | <1%** |

cv=coefficient of variation. Use of Ambulatory Glucose Profile (AGP) for CGM report.

*Some studies suggest that lower %CV targets (<33%) provide additional protection against hypoglycemia for those receiving insulin or sulfonylureas.

**Guidance on targets for assessment of glycemic control is for adults with type 1 or type 2 diabetes.

Time in Range

“Time in range” (TIR) generally refers to the time spent in an individual’s target glucose range¹

- The primary goal for effective and safe glucose control is to increase the TIR while reducing the time below range (TBR)¹
- Each incremental 5% increase in TIR is associated with clinically significant benefits¹

Estimated A1C for a given TIR level^{1,*}

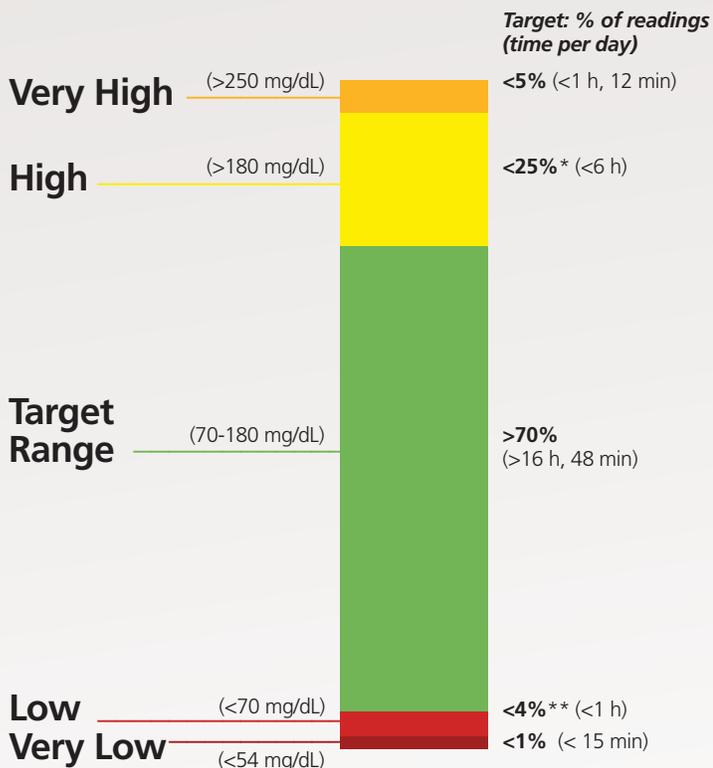
| TIR 70-180 mg/dL | A1C |
|------------------|-------|
| 20% | 10.6% |
| 30% | 9.8% |
| 40% | 9.0% |
| 50% | 8.3% |
| 60% | 7.5% |
| 70% | 6.7% |
| 80% | 5.9% |
| 90% | 5.1% |

Every 10% increase in TIR = ~0.8% A1C reduction.

*Participants with type 1 or type 2 diabetes within 18 randomized controlled trials, n=1,137.

Time in range targets¹

Type 1 & type 2 diabetes

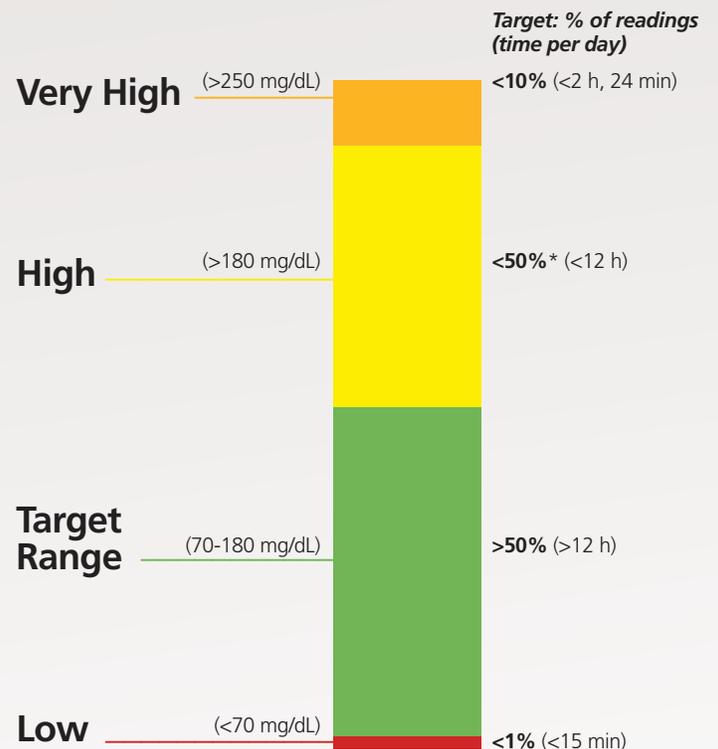


For age <25 years with type 1 diabetes, if the A1C goal is 7.5%, then set TIR target to approximately 60%.

* Includes percentage of values >250 mg/dL.

** Includes percentage of values <54 mg/dL.

Older/high-risk: type 1 & type 2 diabetes



Older and/or high-risk individuals with diabetes are at notably higher risk for severe hypoglycemia due to age, duration of diabetes, duration of insulin therapy, and greater prevalence of hypo unawareness. This is compounded by cognitive and physical impairments and other comorbidities.

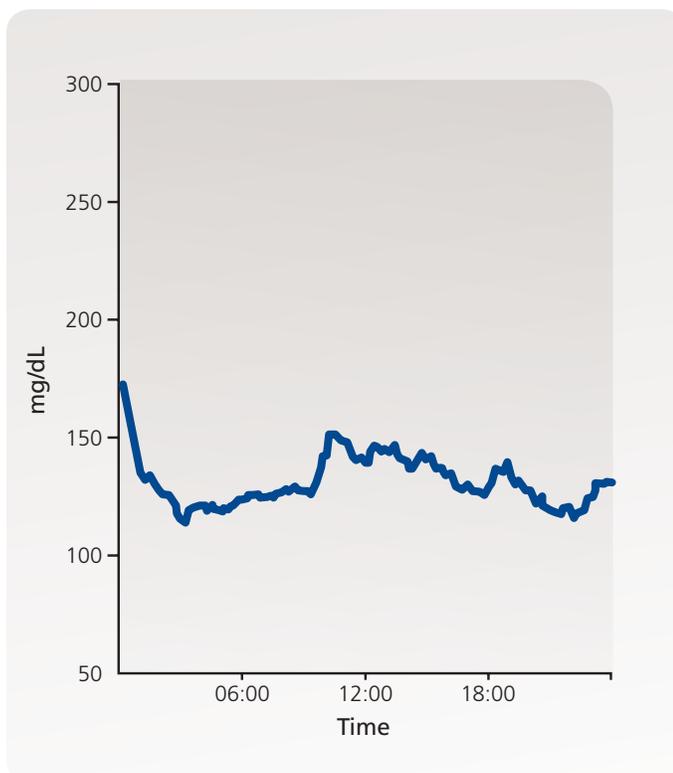
Glucose Variability

- **Glycemic variability** is characterized by the amplitude, frequency, and duration of glucose fluctuations²
- **Predictor of hypoglycemia:** Both the amplitude and the timing of the blood glucose fluctuations contribute to the risks for hypoglycemia and hyperglycemia²
 - Increased glucose variability is consistently associated with mortality in the intensive care unit and is a consistent predictor of hypoglycemia, both in prospective studies and within randomized clinical trials²
- **Coefficient of variation (CV)** is used to quantify glycemic variability²
$$CV = \frac{\text{standard deviation}}{\text{mean}}$$
- **Target:** Stable glucose levels are defined as a CV <36%, and unstable glucose levels are defined as CV ≥36%²
 - Some studies might suggest a target of less than 33% for patients on insulin or sulfonylureas¹

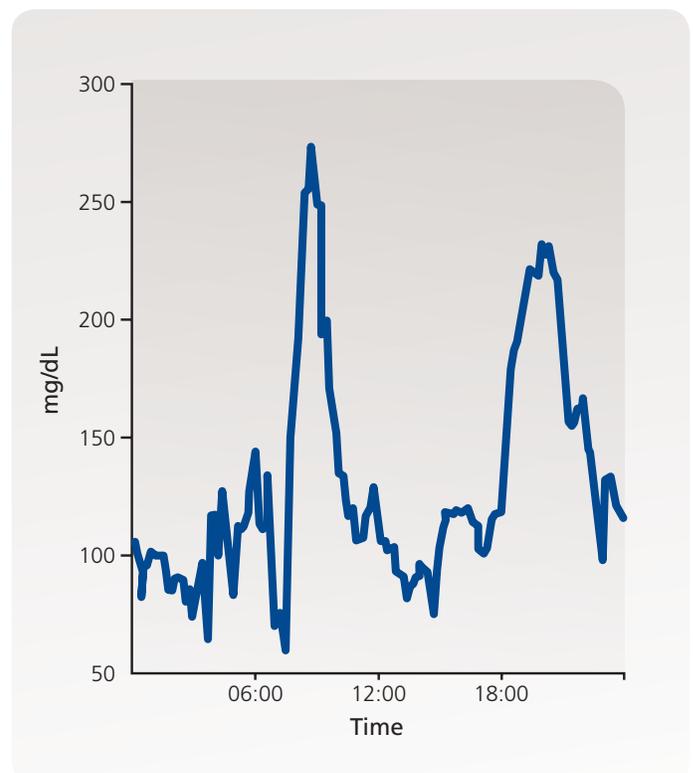
Same A1C, different variability

While these 2 hypothetical patients have the same A1C, their CGM tell a more complete story.

A1C 6.7%, CV 26%



A1C 6.7%, CV 53%



Sample Ambulatory Glucose Profile¹

AGP Report

Name _____
MRN _____

GLUCOSE STATISTICS AND TARGETS

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

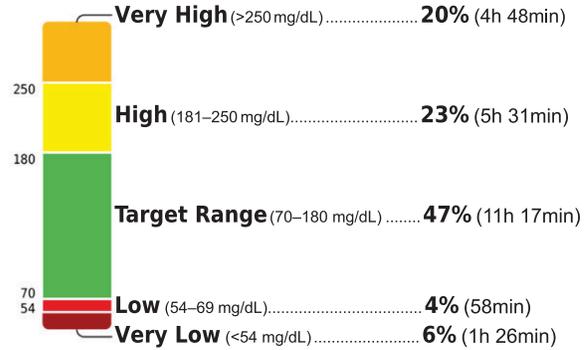
Glucose Ranges **Targets** [% of Readings (Time/Day)]
Target Range 70–180 mg/dLGreater than 70% (16h 48min)
Below 70 mg/dL.....Less than 4% (58min)
Below 54 mg/dL.....Less than 1% (14min)
Above 180 mg/dLLess than 25% (6h)
Above 250 mg/dL.....Less than 5% (1h 12min)

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

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

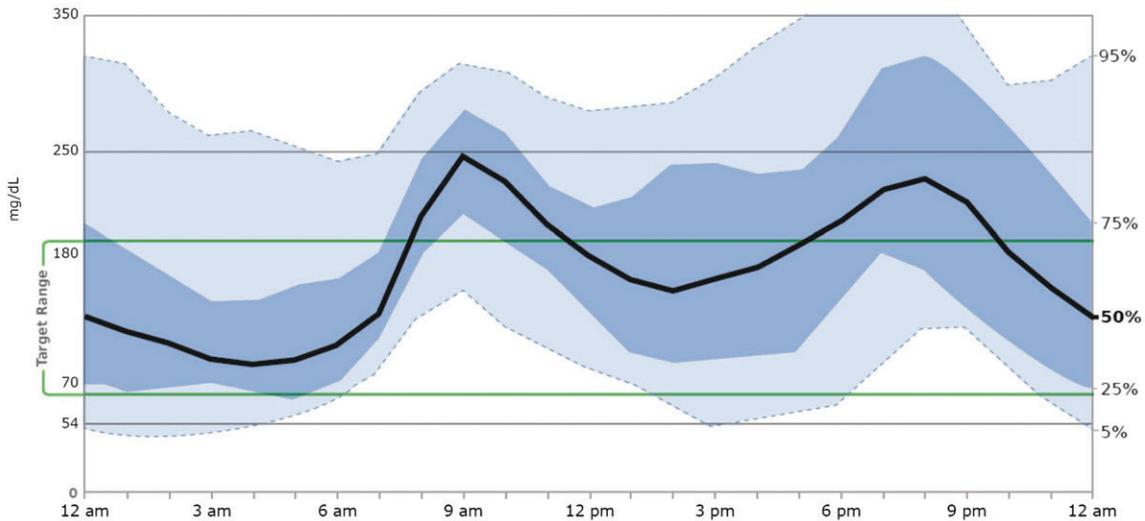
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES

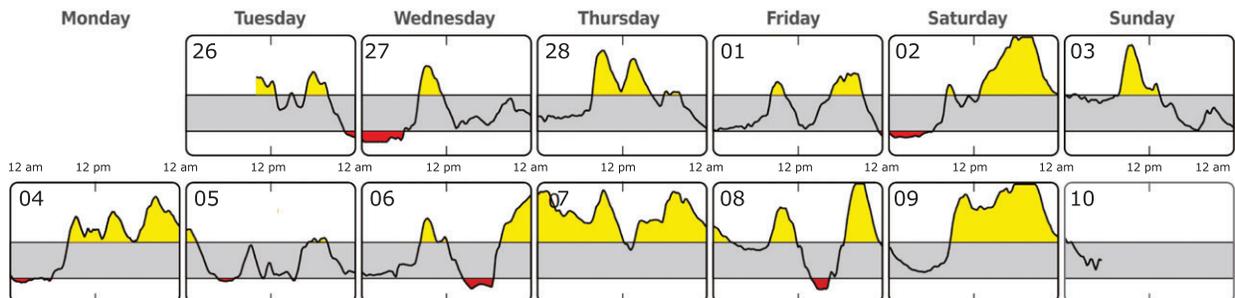


AMBULATORY GLUCOSE PROFILE (AGP)

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.



DAILY GLUCOSE PROFILES



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

References: 1. Battelino T, Danne T, Bergenstal RM, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. *Diabetes Care*. In Press: <https://doi.org/10.2337/dci19-0028>. 2. Danne T, Nimri R, Battelino T, et al. International Consensus on Use of Continuous Glucose Monitoring. *Diabetes Care*. 2017;40:1631–1640.

