

P1752 Working Group Meeting

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

Attendance Taken by Secretary

29 November 2022

Teleconference

Attendance

Attendance is important for determining voting rights, so please remember to “check in” Write full name and affiliation on your zoom name. If you attend only by phone, please email the info to simona@openmhealth.org

Secretary will mark attendance for everyone

If you attended a previous call and your attendance was not noted on the draft minutes distributed by the Secretary, please email simona@openmhealth.org

Voting membership

Attendance is important for determining voting membership

After you've attended 2 consecutive meetings you are eligible for voting membership

If you wish to become a voting member, send an email with the request to simona@openmhealth.org

You don't need to be a voting member to participate in the WG or subgroup calls

You need to be a voting member to move or second motions and to vote whenever the WG entertains a motion (e.g., to approve the agenda, to approve an action by the WG, etc.)

If you miss 2 consecutive meetings, voting membership is revoked and can be gained again by attending 2 consecutive meeting and sending a request

Accommodation can be made for special circumstances, which should be brought to the Chair's attention

Determination of Quorum

Approval of Agenda

1. Attendance
2. Call for Patents, Code of Ethics, Copyright Policy
3. Approval of agenda and minutes (if quorum present)
4. Updates from subgroups and discussion
5. Updated P&P
6. Other business

Approval of Prior Minutes

(October 25, 2022)

IEEE Policies

IEEE SA Call for Patents

Participants have a duty to inform the IEEE

- Participants shall inform the IEEE (or cause the IEEE to be informed) of the identity of each holder of any potential Essential Patent Claims of which they are personally aware if the claims are owned or controlled by the participant or the entity the participant is from, employed by, or otherwise represents
- Participants should inform the IEEE (or cause the IEEE to be informed) of the identity of any other holders of potential Essential Patent Claims

**Early identification of holders of potential
Essential Patent Claims is encouraged**

Slide #1

Ways to inform IEEE

- Cause an LOA to be submitted to the IEEE-SA (patcom@ieee.org); or
- Provide the chair of this group with the identity of the holder(s) of any and all such claims as soon as possible; or
- **Speak up now and respond to this Call for Potentially Essential Patents**

If anyone in this meeting is personally aware of the holder of any patent claims that are potentially essential to implementation of the proposed standard(s) under consideration by this group and that are not already the subject of an Accepted Letter of Assurance, please respond at this time by providing relevant information to the WG Chair

Slide #2

Other guidelines for IEEE WG meetings

- All IEEE-SA standards meetings shall be conducted in compliance with all applicable laws, including antitrust and competition laws.
 - Don't discuss the interpretation, validity, or essentiality of patents/patent claims.
 - Don't discuss specific license rates, terms, or conditions.
 - Relative costs of different technical approaches that include relative costs of patent licensing terms may be discussed in standards development meetings.
 - Technical considerations remain the primary focus
 - Don't discuss or engage in the fixing of product prices, allocation of customers, or division of sales markets.
 - Don't discuss the status or substance of ongoing or threatened litigation.
 - Don't be silent if inappropriate topics are discussed ... do formally object.

For more details, see *IEEE-SA Standards Board Operations Manual*, clause 5.3.10 and
Antitrust and Competition Policy: What You Need to Know at <http://standards.ieee.org/develop/policies/antitrust.pdf>

Slide #3

Patent-related information

The patent policy and the procedures used to execute that policy are documented in the:

- *IEEE-SA Standards Board Bylaws*
(<http://standards.ieee.org/develop/policies/bylaws/sect6-7.html#6>)
- *IEEE-SA Standards Board Operations Manual*
(<http://standards.ieee.org/develop/policies/opman/sect6.html#6.3>)

Material about the patent policy is available at
<http://standards.ieee.org/about/sasb/patcom/materials.html>

If you have questions, contact the IEEE-SA Standards
Board Patent Committee Administrator at
patcom@ieee.org

Slide #4

IEEE SA Copyright Policy

IEEE SA Copyright Policy (November 2019)

- By participating in this activity, you agree to comply with the [IEEE Code of Ethics](#), all applicable laws, and all IEEE policies and procedures including, but not limited to, the IEEE SA Copyright Policy.
 - Previously Published material (copyright assertion indicated) shall not be presented/submitted to the Working Group nor incorporated into a Working Group draft unless permission is granted.
 - Prior to presentation or submission, you shall notify the Working Group Chair of previously Published material and should assist the Chair in obtaining copyright permission acceptable to IEEE SA.
 - For material that is not previously Published, IEEE is automatically granted a license to use any material that is presented or submitted.

IEEE SA Copyright Policy

- The IEEE SA Copyright Policy is described in the IEEE SA Standards Board Bylaws and IEEE SA Standards Board Operations Manual
- IEEE SA Copyright Policy, see
 - Clause 7 of the IEEE SA Standards Board Bylaws
<https://standards.ieee.org/about/policies/bylaws/sect6-7.html#7>
 - Clause 6.1 of the IEEE SA Standards Board Operations Manual
<https://standards.ieee.org/about/policies/opman/sect6.html>
- IEEE SA Copyright Permission
 - <https://standards.ieee.org/content/dam/ieee-standards/standards/web/documents/other/permissionltrs.zip>
- IEEE SA Copyright FAQs
 - <http://standards.ieee.org/faqs/copyrights.html/>
- IEEE SA Best Practices for IEEE Standards Development
 - http://standards.ieee.org/develop/policies/best_practices_for_ieee_standards_development_051215.pdf
- Distribution of Draft Standards (see 6.1.3 of the SASB Operations Manual)
 - <https://standards.ieee.org/about/policies/opman/sect6.html>

IEEE SA Individual Participation

Participant behavior in IEEE-SA activities is guided by the IEEE Codes of Ethics & Conduct

- All participants in IEEE-SA activities are expected to adhere to the core principles underlying the:
 - IEEE Code of Ethics
 - IEEE Code of Conduct
- The core principles of the IEEE Codes of Ethics & Conduct are to:
 - *Uphold the highest standards of integrity, responsible behavior, and ethical and professional conduct*
 - *Treat people fairly and with respect, to not engage in harassment, discrimination, or retaliation, and to protect people's privacy.*
 - *Avoid injuring others, their property, reputation, or employment by false or malicious action*
- The most recent versions of these Codes are available at <http://www.ieee.org/about/corporate/governance>

Participants in the IEEE-SA “individual process” shall act independently of others, including employers

- The [IEEE-SA Standards Board Bylaws](#) require that “participants in the IEEE standards development individual process shall act based on their qualifications and experience”
- This means participants:
 - **Shall act & vote** based on their personal & independent opinions derived from their expertise, knowledge, and qualifications
 - **Shall not act or vote** based on any obligation to or any direction from any other person or organization, including an employer or client, regardless of any external commitments, agreements, contracts, or orders
 - **Shall not direct** the actions or votes of other participants or retaliate against other participants for fulfilling their responsibility to act & vote based on their personal & independently developed opinions
- By participating in standards activities using the “individual process”, you are deemed to accept these requirements; if you are unable to satisfy these requirements then you shall immediately cease any participation

IEEE-SA standards activities shall allow the fair & equitable consideration of all viewpoints

- The [IEEE-SA Standards Board Bylaws](#) (clause 5.2.1.3) specifies that *“the standards development process shall not be dominated by any single interest category, individual, or organization”*
 - This means no participant may exercise *“authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints”* or *“to hinder the progress of the standards development activity”*
- This rule applies equally to those participating in a standards development project and to that project’s leadership group
- Any person who reasonably suspects that dominance is occurring in a standards development project is encouraged to bring the issue to the attention of the Standards Committee or the project’s IEEE-SA Program Manager

Update from Subgroups

P1752.2 Cardiorespiratory Subgroup

October 27 and November 17, 2022

Presentations: Continuation and follow up of

“Physical Activity & Recovery - The Cardiorespiratory Response and Mobile Health Use Cases”

Discussions:

- Other considerations about exercise physiology and cardiorespiratory fitness (CRF) *
- Timely use case: AHA & PAA (*stakeholders with expertise*) → HL7 FHIR Construct
 - ❖ *“Physical Activity Implementation Guide”*
 - ❖ Implementation to enable fitness assessment as a *‘vital sign’*
- Continuum of health metrics utilization:
 - ❖ *Performance & fitness → Wellness → Aging & ‘pre’-disease → Disease*
- Need for reference document about value proposition for Open mHealth
Cardiorespiratory schema to be developed with conciseness/clarity... examples:
 - ❖ Lightweight interoperable cardiorespiratory data standard
 - ❖ Data contextuality enabled by broadbased Open mHealth mandate

Physical Activity / Exercise

Cardiorespiratory

Intensity

Movement

Light Activity

Aerobic Exercise

Vigorous Exercise

General Classifications



Variables of Interest*

Hemodynamics

BP, P, TPR, Q

Respiratory

BP, P, TPR, Q

Gas Exchange

RR, TV, Ventilation

Autonomics

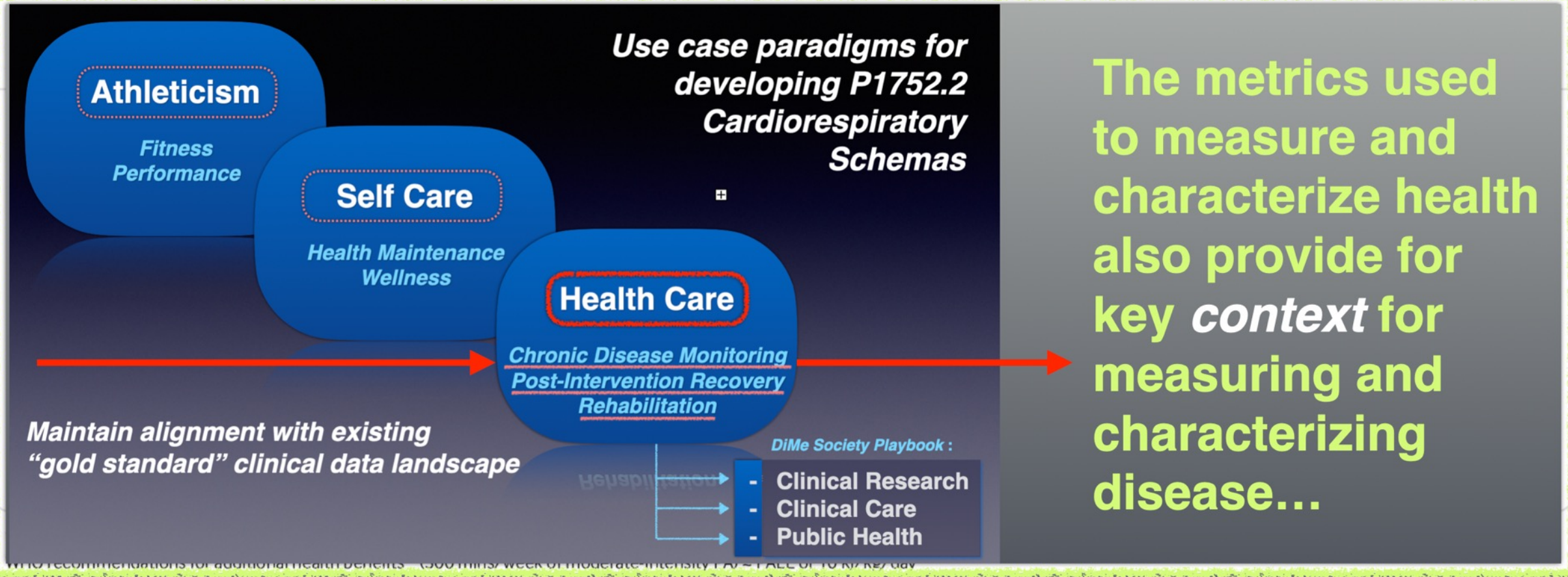
HR, HRV metrics

Symptoms

Rate perceived exertion

Emphasis 2:

Physical Activity Trajectories and Mortality



P1752.2 Cardiorespiratory Subgroup

October 27 and November 17, 2022

Action items:

- Presentation focus on contextuality, and accommodation of multivariate / multiscale data assessments
- Input request for draft of the Open mHealth Cardiorespiratory document key value propositions: <https://ieee-sa.imeetcentral.com/omh/folder/WzlwLDkxNjlwNjVd>
- Preparation of strategy for active orientation of key stakeholders to win awareness and committed engagement (upcoming conference venues discussed).
- Continue focus to identify *priority* use case proposals to facilitate relevant schema development

Cardiorespiratory subgroup:

- Workgroup meeting time moved to 3rd Thursday of each month to better avoid conflicting holidays...
- **Next call:** [December 15, 2022, @ 17:00 UTC \(9:00 AM Pacific\)](#)

P1752.2 Metabolic Subgroup

Starting point: Driving 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

P1752.2 Metabolic Subgroup

- What are the important measures currently being used? → P1752.2 schemas
- Relevant literature, partner groups
 - <https://www.diabetestechology.org/icode/>
- Two major types of measures
 - Self-monitored blood glucose (SMB): discrete measures
 - Continuous glucose monitoring (CGM): continuous measures, concept of glycemic variability
- Product: Set of draft schemas to be presented to WG in January
 - Definitions
 - Units of measure
 - Contextual elements

CGM: 2019 Consensus

Table 2

Standardized CGM metrics for clinical care: 2019

-
- | | |
|--|----------|
| ➔ 1. Number of days CGM worn (recommend 14 days) (42,43) | |
| ➔ 2. Percentage of time CGM is active (recommend 70% of data from 14 days) (41,42) | |
| 3. Mean glucose | |
| 4. Glucose management indicator (GMI) (75) | |
| 5. Glycemic variability (%CV) target $\leq 36\%$ (90)* | |
| 6. Time above range (TAR): % of readings and time >250 mg/dL (>13.9 mmol/L) | Level 2 |
| 7. Time above range (TAR): % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L) | Level 1 |
| 8. Time in range (TIR): % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L) | In range |
| 9. Time below range (TBR): % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L) | Level 1 |
| 10. Time below range (TBR): % of readings and time <54 mg/dL (<3.0 mmol/L) | Level 2 |

Use of Ambulatory Glucose Profile (AGP) for CGM report

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/>

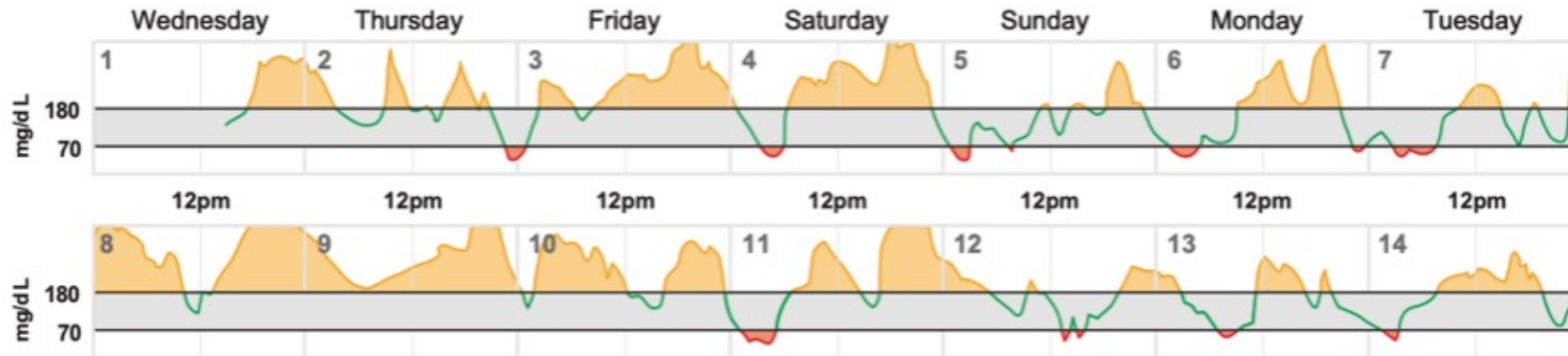
Percentage coefficient of variation for glucose

$\%CV = [(SD \text{ of glucose}) / (\text{mean glucose})]$

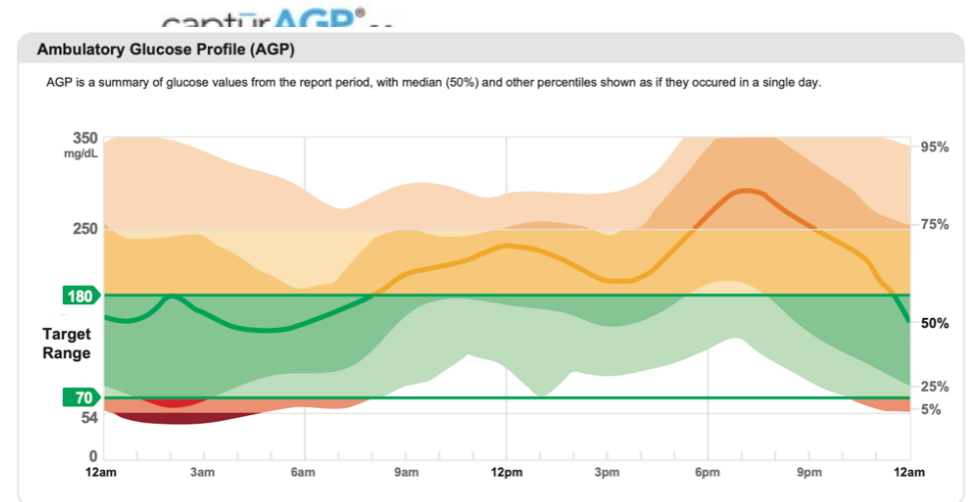
CGM Readings

Daily Glucose Profiles

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

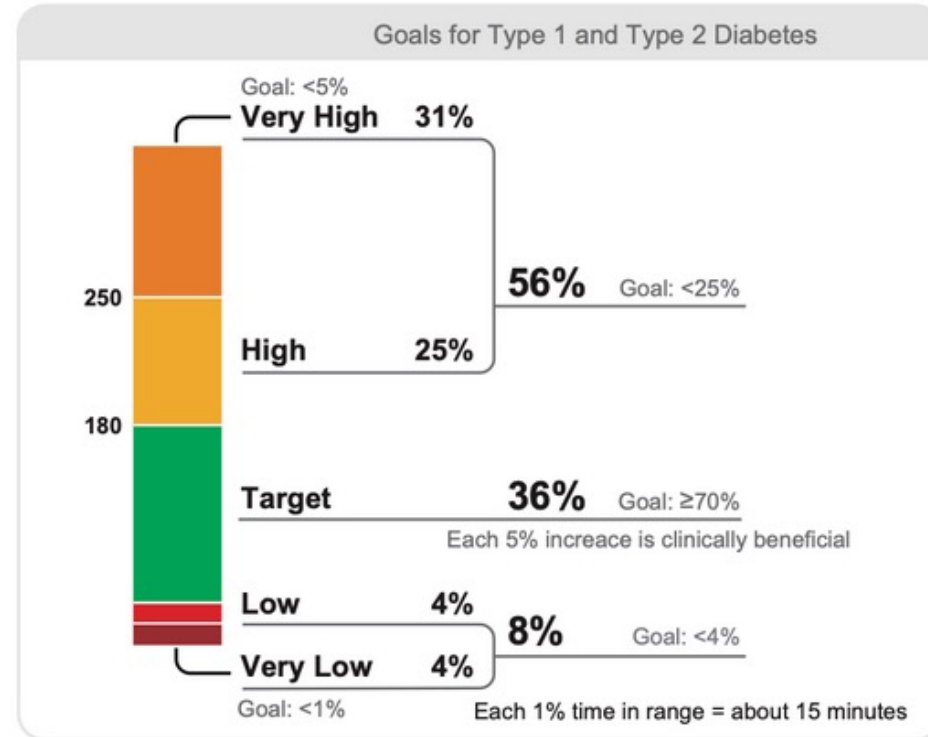


Patent Pending - HealthPartners Institute dba International Diabetes Center – All Rights Reserved. ©2022



Ambulatory Glucose Profile CGM - v5.0

AGP Report: Continuous Glucose Monitoring



Test Patient

DOB: Dec. 10, 1975

14 Days: September 1 - September 14, 2021

Time CGM Active: 94.6%

Glucose Metrics

Average Glucose **201 mg/dL**
Goal: <154 mg/dL

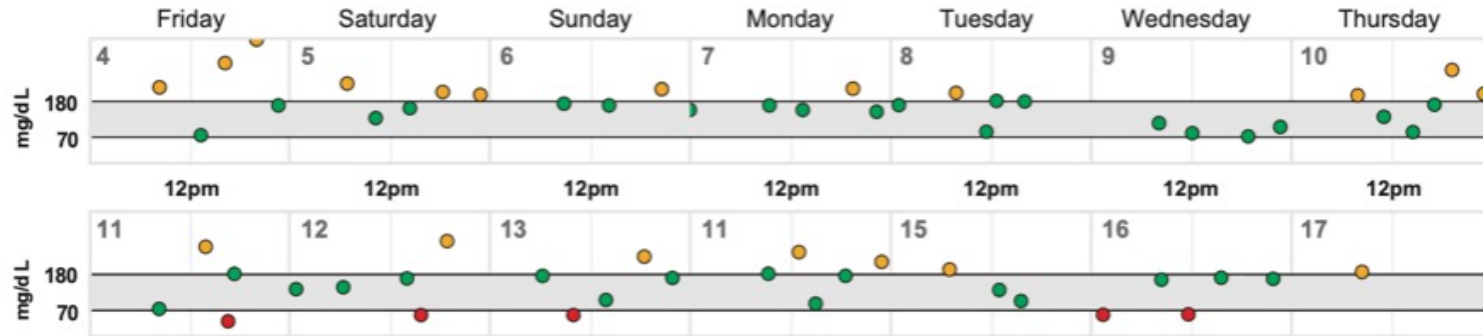
Glucose Management Indicator (GMI) **8.1%**
Goal: <7%

Glucose Variability **45.2%**
Defined as percent coefficient of variation
Goal: ≤36%

SMBG Readings

Daily Glucose Profiles (Last 2 Weeks)

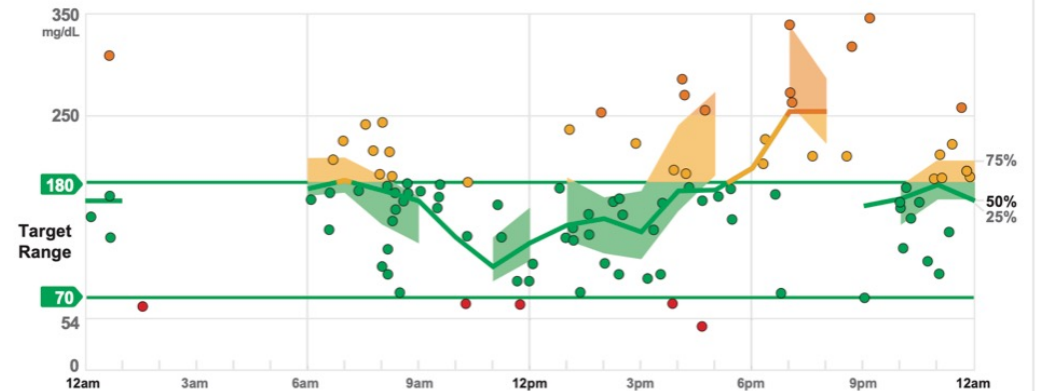
Each daily profile represents a midnight-to-midnight period. The more readings available throughout the day the more opportunities for improvement.



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Ambulatory Glucose Profile (AGP)

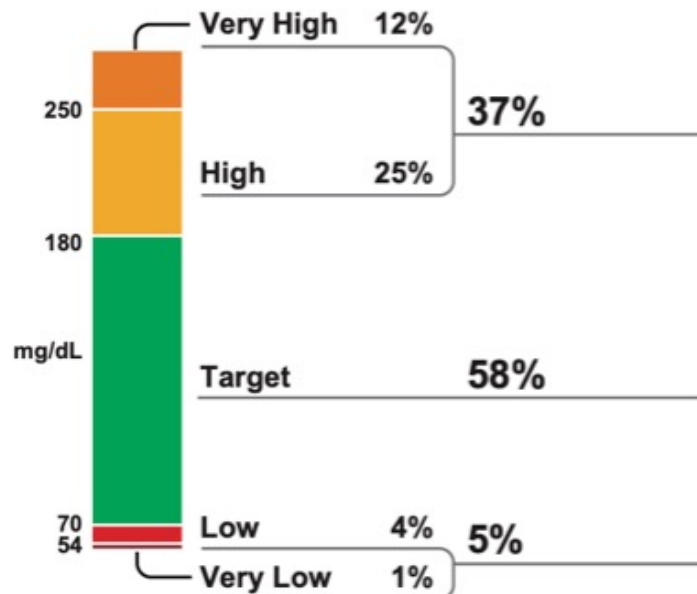
AGP is a summary of glucose readings from the report period based on blood glucose monitoring (BGM) data with median (50%), 25th and 75th percentiles shown as if they occurred in a single day.



Ambulatory Glucose Profile SMBG - v5.0

AGP Report: Blood Glucose Monitoring

Percent BGM Readings in Ranges



Test Patient

DOB: Dec. 10, 1975

31 Days: May 17 – June 17, 2021

BGM Statistics

Number of Readings	130
Average Readings/Day	3.3
Average Glucose	171 mg/dL
Average Before-Meal Glucose	Unable to Calculate
Fasting and Before-Meal Target	70–130 mg/dL
Average After-Meal Glucose	Unable to Calculate
After-Meal Target	Less than 180 mg/dL
Lowest/Highest Glucose	43/354 mg/dL
Glucose Variability	37.4%
Defined as percent coefficient of variation	
Goal: ≤36%	

Proposed P1752.2 Blood Glucose Schemas

- Initial set of measures
 - Blood glucose
 - Blood glucose unit-value (mg/dL, mmol/L)
 - Time in range [TIR], above range [TAR], below range [TBR]
 - Blood glucose thresholds (cut-off values for low, very low, high and very high)
 - [Ambulatory Glucose Profile for CGM](#)
 - [Ambulatory Glucose Profile for SMBG](#)
- Contextual measures
 - CGM
 - percent_time_sensor_active
 - number_of_days_device_worn
 - SMBG
 - number_of_readings
 - average_readings_per_day

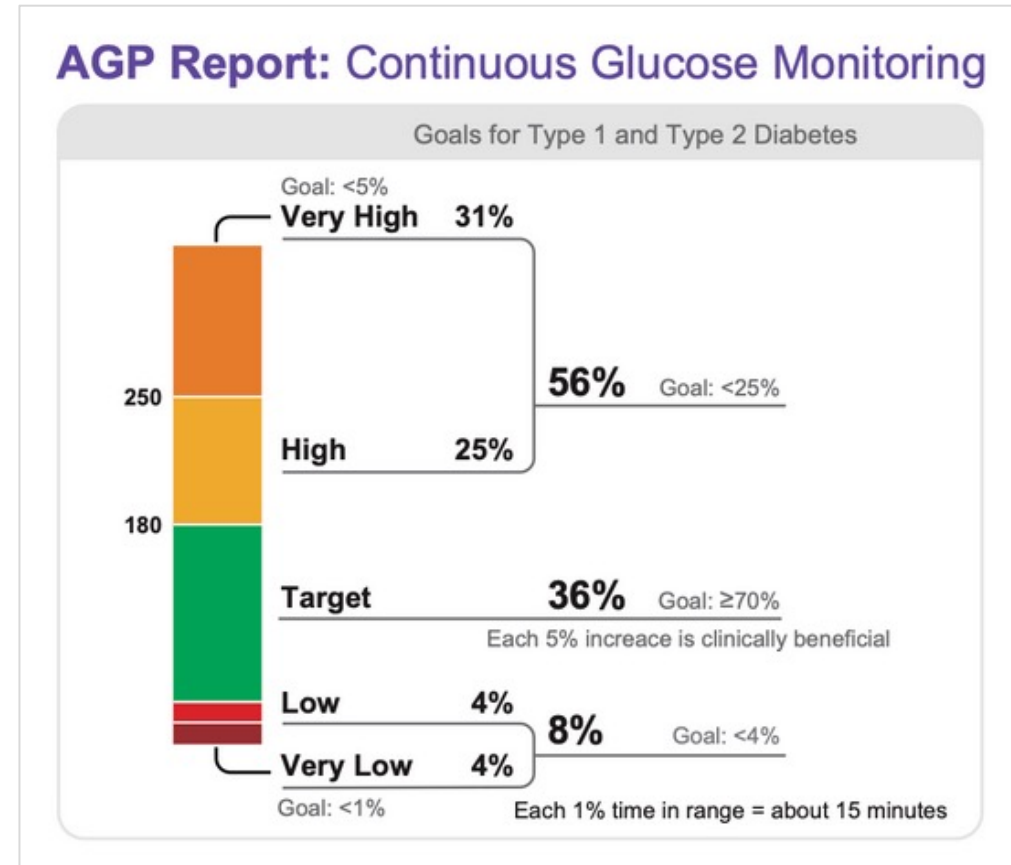
Issue #1: Range and Thresholds

Time in Range

- Need denominator
- Sparsity of data

Modeling as ranges vs thresholds

- the intervals
- the threshold values



Issue #2: Contextual measures

- Contextual measures
 - CGM
 - percent_time_sensor_active
 - number_of_days_device_worn
 - SMBG
 - number_of_readings
 - average_readings_per_day

Metadata vs clinical context that belongs in the schema itself

- Required for clinical interpretation for BG but not necessarily for other measures (e.g., steps)
- Can't make elements optional vs required in metadata
- Sets up potential conflict if we ever want to add sensor time worn to metadata (e.g., for HRV)

Issue #3: Temporal relationships

Already in Open mHealth and will be used

- Temporal relationship to meal
- Temporal relationship to sleep
- Temporal relationship to physical activity
 - e.g., before exercise, after exercise

Discussed and rejected

- Temporal relationship to doses of antihyperglycemic medications
 - challenging: large variety of medications and dosing regimens

Revised EMB Policies and Procedures

Summary of Action Items

Future Meetings

Upcoming Meetings

- P1752.2 WG call
 - Tuesday January 17 at 8 am Pacific
- Cardio-respiratory subgroup:
 - Thursday December 15 at 9 am Pacific
- Metabolic subgroup:
 - Tuesday January 10 at 8 am Pacific

Adjournment