

P1752 Working Group Meeting

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

Attendance Taken by Secretary

28 February 2023

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

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

Determination of Quorum

Approval of Agenda

1. Attendance
2. Call for Patents, Copyright Policy, Code of Ethics
3. Approval of agenda and minutes (if quorum present)
4. Updates from CR subgroup
5. Blood Glucose schemas
6. Other business

Approval of Prior Minutes

(January 17, 2023)

Update from Subgroups

P1752.2 Cardiorespiratory Subgroup

January 26th and February 23rd, 2023

Action items:

- Request for cardiorespiratory schema structure proposals
 - Facilitate contextuality (existing P1752 schemas)
 - Accommodate metrics spanning broadest and most impactful use cases:
Fitness & performance -> Health -> Aging & “pre”-disease -> Disease
 - Optimize granularity
 - Enable common metrics relied upon in health care delivery, or otherwise allow for extensibility
 - Aspirational: Accommodate (*but not mandate*) multivariate / multiscale data assessments?
 - Accommodate the broadening scope of what is “Mobile Health Data” ***
- Strategy for active orientation of key stakeholders to win awareness and committed engagement

Cardiorespiratory subgroup:

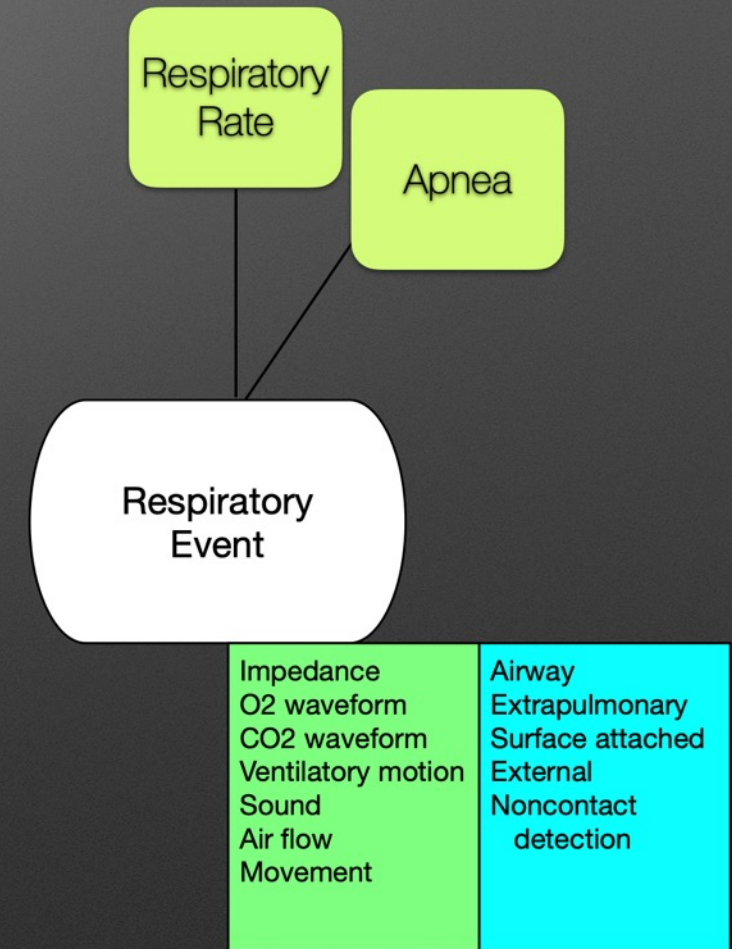
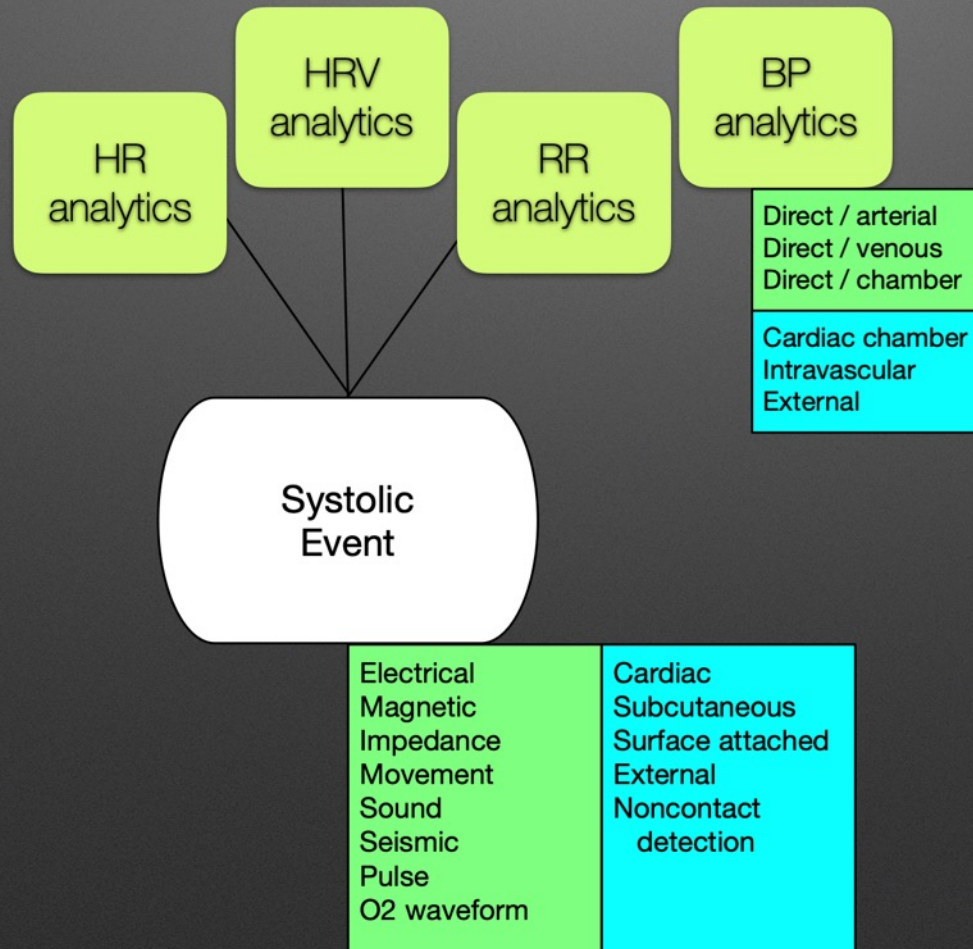
- **Next call:** March 23, 2023, @ 16:00 UTC (9:00 AM Pacific) ... *Daylight Savings Time*

Proposal

- Tiered Structure for the Cardiac Schema
- Separate schemas for Cardiac and Respiratory

Tier 1:
Derived *or*
declared

Tier 0:
Currency
(*granularity*)



P1752.2 Metabolic Subgroup

- What are the important measures currently being used? → P1752.2 schemas
- 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
 - Definitions
 - Units of measure
 - Contextual elements

Proposed P1752.2 Blood Glucose Schemas

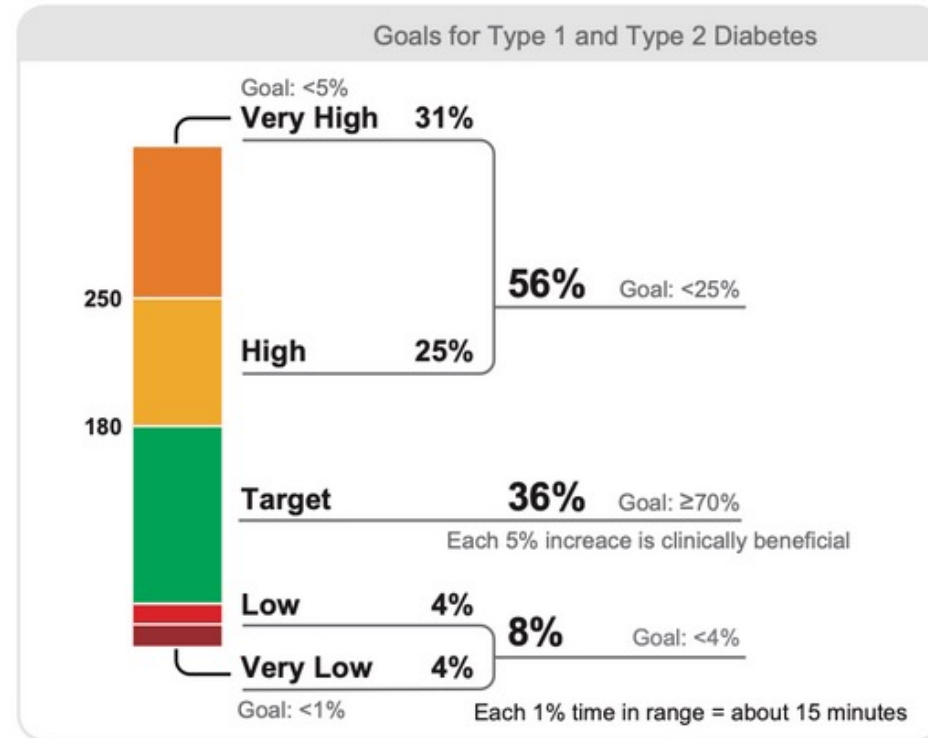
- Initial set of measures presented 1/17/23 and shared with WG
 - Blood glucose
 - Blood glucose unit-value (mg/dL, mmol/L)
 - Blood glucose thresholds (cut-off values for low, very low, high and very high)
 - Time in range [TIR], above range [TAR], below range [TBR] [addendum proposed today](#)
- Contextual measures
 - CGM
 - percent_time_sensor_active
 - number_of_days_device_worn
 - SMBG
 - number_of_readings
 - average_readings_per_day

Proposed P1752.2 Blood Glucose Schemas

- Initial set of measures (part 2)
 - Blood glucose management indicator (GMI) for CGM
 - Blood glucose variability as coefficient of variation (CV)
 - [Ambulatory Glucose Profile for CGM](#)
 - [Ambulatory Glucose Profile for SMBG](#)

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%

Ambulatory Glucose Profile CGM (older version)

AGP Report

Name _____

MRN _____

GLUCOSE STATISTICS AND TARGETS

26 Feb 2019 - 10 Mar 2019

13 days

% Time CGM is Active

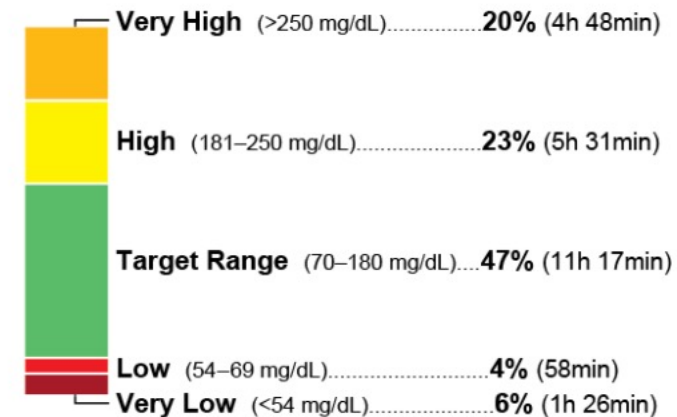
99.9%

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.	

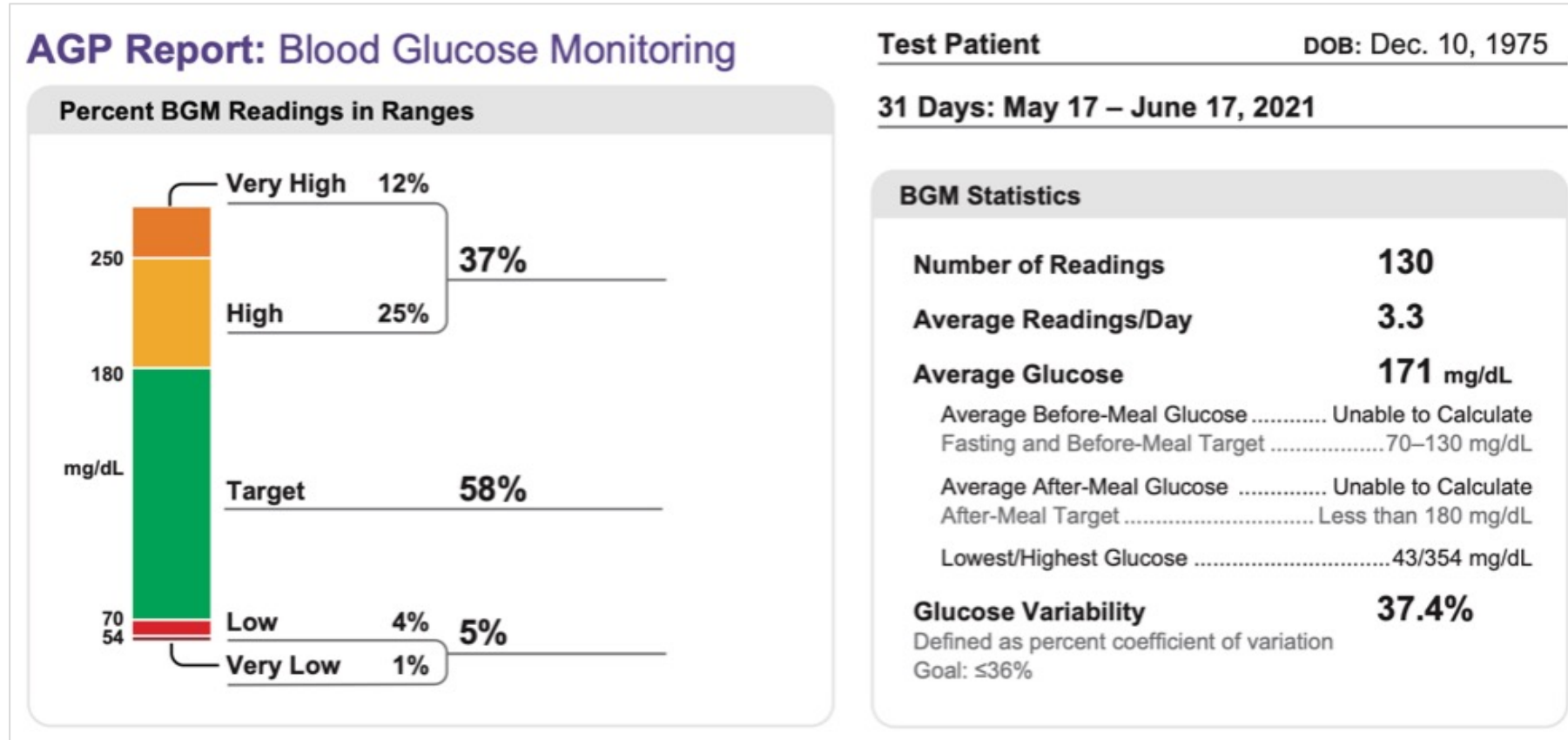
Average Glucose	173 mg/dL
Glucose Management Indicator (GMI)	7.6%
Glucose Variability	49.5%

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

TIME IN RANGES



Ambulatory Glucose Profile SMBG - v5.0

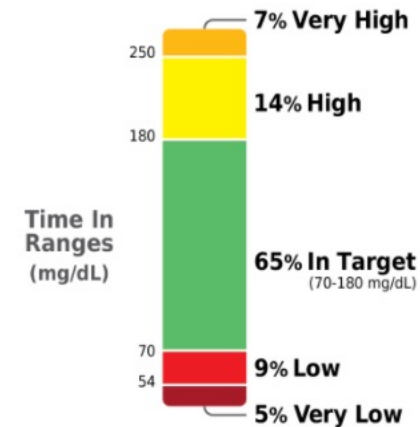


Ambulatory Glucose Profile SMBG (older version)

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



Summary of Action Items

Future Meetings

Upcoming Meetings

- P1752.2 WG call
 - Tuesday April 4 at 8 am Pacific
- Cardio-respiratory subgroup:
 - Tuesday March 7 at 9:00 am Pacific: extra session on schema development
 - Thursday March 23 at 9:00 am Pacific
- Metabolic subgroup:
 - Tuesday March 14 at 8 am Pacific

Adjournment