

P1752 Working Group Meeting

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

Attendance Taken by Secretary

4 April 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 <u>request</u> to <u>simona@openmhealth.org</u>

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 <u>shall</u> 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 <u>should</u> 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 <u>IEEE Code of Ethics</u>, 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 <u>IEEE-SA Standards Board Bylaws</u> 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 <u>IEEE-SA Standards Board Bylaws</u> (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 subgroups
- 5. Other business

Approval of Prior Minutes

(February 28, 2023)

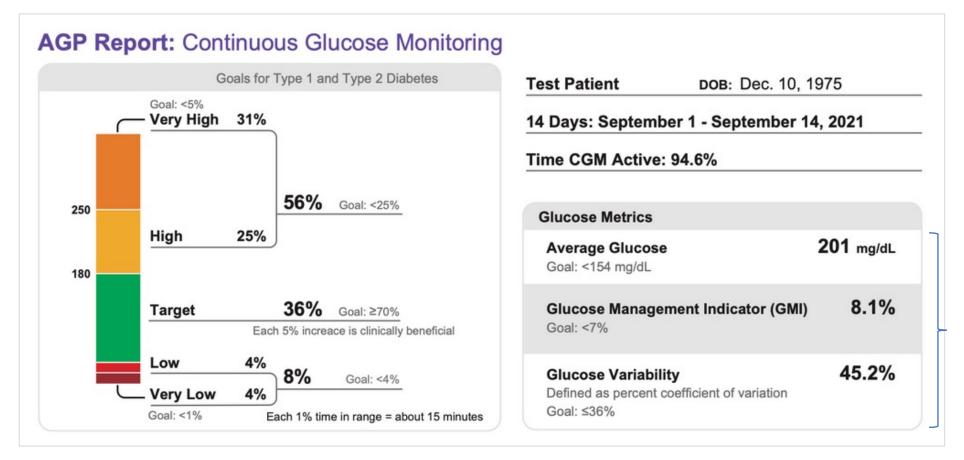
Update from Subgroups

P1752.2 Metabolic Subgroup

- Additional consideration regarding threshold values and AGP
 - Modeled generic threshold schema
 - Modeling additional data elements in AGP for SMBG v5.0: discussed using named elements or nested structure (i.e., array of values including, min, max, average pre/post meal → decided to revisit modeling AGP
 - Can we use time-in-range schema to model most important parts of AGP?
 - Proposal: Draft modeling AGP as an implementation guide rather than schema



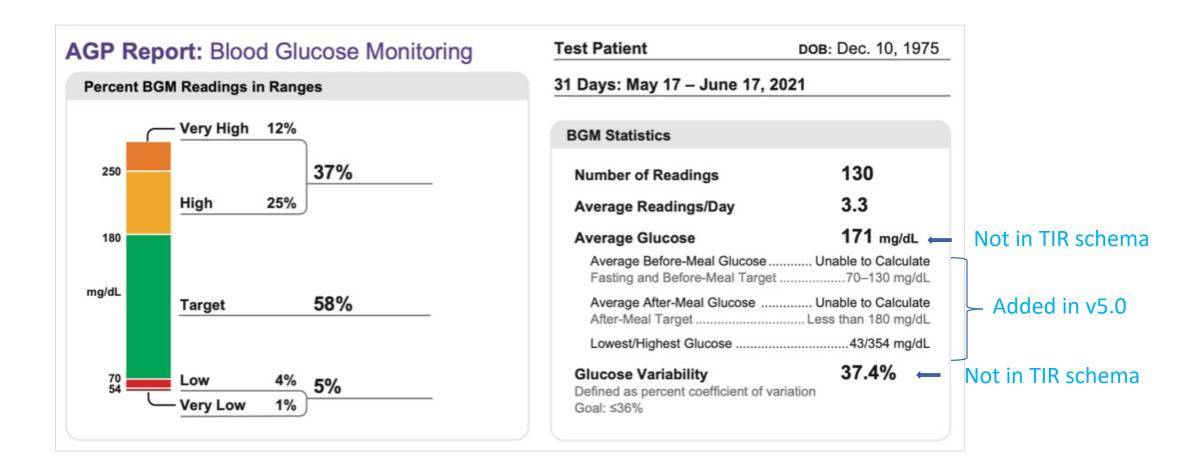
Ambulatory Glucose Profile CGM - v5.0



schema

Not in TIR

Ambulatory Glucose Profile SMBG - v5.0



P1752.2 Metabolic Subgroup

- Food intake (important for BG measures)
 - Modeling food intake: should the WG do that?
 - As currently the source is self-report, would that be a food diary?
- Body weight and related measures
 - Smart scales present various measurements, e.g., body fat %
 - Body weight may be the only measure of interest for a use case, e.g., weight management clinic, but other measures may be of interest in other use cases, e.g., a sport clinic
 - A schema does not validate the measure it models



Standard for Mobile Health Data

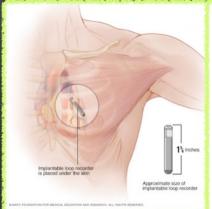
Expansion of Mobile Health Data overlapping into the Digital Biomarker Space...



Wearables & Internal/implant sensors*











Compatible extensibility layers **Proposal** Tiered Structure for the Cardiac Schema Separate schemas for Cardiac and Respiratory Tier 1: Respiratory Derived or analytics analytics Rate Apnea declared analytics analytics Direct / venous Direct / chamber Tier 0: Systolic Respiratory Event Event Currency (granularity) O2 waveform Subcutaneous CO2 waveform Surface attached Surface attached External External Noncontact detection Air flow detection Movement O2 waveform

Future Proofing

Enhanced clinical relevance

Examples:

- Differentiate atrial, atrial-paced, ventricular, ventricular paced (all types)
- Waveform morphology analytics

P1752.2 Cardiorespiratory Subgroup

March 23rd, 2023

Items:

- Use cases: Health -> Aging and "pre"-disease -> Disease
- Assessing dependencies: Cardiorespiratory schema structuring
 - · Proposal 1 discussion continued
 - Schema: Accommodation of layers
- Schema writing (informed by P1752.1 schemas)
 - Especially informed by existing Metadata and Utility schemas

Other business

- NHLBI: "Transforming Hypertension Diagnosis and Management in the Era of AI"
 - Contextuality
 - · Cuff / cuffless
 - Effective data acquisition, preparation, and labeling": 90% of the Al task
- Next meeting: 9AM PST on April 27, 2023



Summary of Action Items

Future Meetings

Upcoming Meetings

- P1752.2 WG call
 - Tuesday May 23 at 8 am Pacific
- Cardio-respiratory subgroup:
 - Thursday April 27 at 9:00 am Pacific
- Metabolic subgroup:
 - Tuesday April 18 at 8 am Pacific



Adjournment