

P1752 Working Group Meeting

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

Attendance Taken by Secretary

24 October 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

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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

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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. Discussion and vote on publishing draft BG-related schemas
- 5. Updates from subgroups
- 6. Other business

Approval of Prior Minutes

(August 29, 2023)

Discussion and vote on publishing draft Blood Glucose-related schemas

Blood glucose and related measures

- Blood glucose and related measures
- blood-glucose.json
- blood-glucose-management-indicator.json
- blood-glucose-threshold-values.json
- blood-glucose-time-in-range.json
- o blood-glucose-unit-value.json
- blood-glucose-variability.json
- ambulatory_glucose_profile_cgm.json



Additional schemas and sample data

- Value sets for properties defined in the schemas above
- specimen-source.json
- temporal-relationship-to-meal.json
- temporal-relationship-to-physical-activity.json
- temporal-relationship-to-sleep.json
- Generic schema
- threshold-values.json
- A set of sample data
- blood-glucose-sample-data.json



Motion to approve & publish as draft on repository

If approved, we will:

- Create a separate branch from main
- Gather Contributor License Agreement as needed (CLA)
- Publish draft schemas there (as version 0.1)
- Same for sample data
- Share and gather feedback
- Add disclaimer



Update from Subgroups

P1752.2 Cardiorespiratory Subgroup

Meeting of Oct 5, 2023

Items of Discussion:

- Discussion of progress/challenges on JSON coding:
 - 1. Respiratory & plethysmography schema
 - 2. Blood pressure & hemodynamics schema
 - 3. Pulse & rhythm schema (see below)
 - <u>Tier 0</u> (granular: in support derivations and research)
 - Tier 1 (basics: declared and/or derived metrics, ventricular-based)
 Vsys sequence class
 - <u>Tier 2</u> (extensibility for clinical relevance: clinical rhythms) Rhythm descriptor classes
 - 4. Focus on Tier 1 properties
 - heartRate.derivation (declared*, manual, derived)
 - heartRate.signalType (electrical, motion, pressurePulse, acoustic, perfusion, unknown*)
 - heartRate.sensingLocation (? location schema ?)
- Challenges encountered in pulse dynamics/rhythm schemas discussed
 - Optimize representation of data series (arrays, objects, +/- nesting) for compactness & simplicity
 - JSON schema coding limitations (data structure complexity & dependencies)
 - Maintaining perspective (i.e. what is best suited to anticipated data workflows and utilization)



P1752.2 Cardiorespiratory Subgroup

Meeting of Oct 5, 2023

Action Items:

- Schema task groups : Monthly status updates
 - 1. Respiratory & plethysmography
 - 2. Blood pressure & hemodynamics
 - 3. Pulse & rhythm schema
- Key considerations:
 - 1. Facilitate the enablement of common metrics relied upon in health care delivery, and otherwise allow for extensibility
 - 2. Accommodate broadening scope of what is "Mobile Health Data" / compatibility with "ground truth" (common source such as implanted medical grade sensors)

Cardiorespiratory subgroup:

Next call:

November 2, 2023 @ 8:00 AM Pacific

DST in most of Europe ends October 29 DST in US ends November 5





P1752.2 Metabolic Subgroup

- Body weight and related measures
 - Drafted body weight components as optional elements of body weight schema + new measures to address limitations of BMI
 - Considerations about those measures (plan to explain in standard document)
 - Draft schemas to be shared with WG after this meeting (already on iMeet)
- Food intake
 - Modeling amounts of macro- and micro-nutrients of meal/snack in progress

Summary of Action Items

Future Meetings

Upcoming Meetings

- P1752.2 WG call
 - Tuesday December 5 at 8 am Pacific
- Cardio-respiratory subgroup:
 - Thursday November 2 at 8:00 am Pacific
- Metabolic subgroup:
 - Tuesday October 31 at 8 am Pacific

Adjournment