

P1752 Working Group Meeting

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

Attendance Taken by Secretary

13 September 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 <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



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. Other business

Approval of Prior Minutes

(July 26, 2022)

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





Update from Subgroups

P1752.2 Cardiorespiratory Subgroup (I)

August 25, 2022

Agenda

Attendance and introductions Review of prior minutes, approved Presentation:

Presentation by C. McCraw:

"Recovery from Physical Activity - The Cardiorespiratory Response and Mobile Health Use Cases"

Questions and discussion



P1752.2 Cardiorespiratory Subgroup (II)

August 25, 2022

Stakeholder involvement:

- Reference authoritative guidelines relevant to specific use case and use case paradigm
- Topical use case experts
- HRX San Diego (September 8-10, 2022): Publicize to relevant industry members, physicians & scientists, IT 3rd party services, user, etc. represented at this meeting (cardiorespiratory domain)

Action items:

- Continuation (part 2) of "Recovery from Physical Activity The Cardiorespiratory Response" presentation
- Other use case proposals fitting the Health Care paradigm: Volunteer

Next call: September 29, 2022, @ 15:00 UTC (8:00 AM Pacific)Information at: https://sagroups.ieee.org/1752/cardio-respiratory-subgroup/

IEEE STANDARDS ASSOCIATION



P1752.2 Metabolic Subgroup

- Working on schemas for an initial set of measures
 - Definitions
 - Units of measure
- Glucose (mg/dL)
- Time in range (%) [TIR] http://www.agpreport.org/agp/agpreports
- Time above range [TAR] / Time below range [TBR]
- Percentage coefficient of variation for glucose (%CV = [(SD of glucose)/(mean glucose)]
- Glucose Management Indicator (GMI)

P1752.2 Metabolic Subgroup

Discussed the scope of schemas (see upcoming slides)

- Resources
 - Existing <u>IEEE 1752.1 schemas</u>
 - Existing Open mHealth schemas

Next call: Tuesday, September 20 at 8 am Pacific https://sagroups.ieee.org/1752/metabolic-subgroup/



What Schemas Do (and Don't)

Overview of Schemas

- FORMAT: A schema is a template for instance data, defining how instance data should look like and what it means
- PROPERTIES: A schema defines required and contextually relevant data (e.g., body position when a blood pressure measure is made)
- VALUE SETS: A schema may include permissible value sets for a property
- 1752.1 schemas are written in JSON Schema <u>https://json-schema.org/</u>
- 1752.1 schemas and sample data are available on the repository https://opensource.ieee.org/omh/1752/-/tree/main



Units of measure

- unit-value.json: a generic schema that defines the combination of a number and its unit of measure as an object with two properties
 - 1. value of type *number*
 - 2. unit of type *string*
- It also requires both value and unit for data to be compliant https://opensource.ieee.org/omh/1752/-/blob/main/schemas/utility/unit-value-1.0.json
- Unit of measure schemas are listed in the Utility folder https://opensource.ieee.org/omh/1752/-/tree/main/schemas/utility



Example: Duration unit value

- duration-unit-value schema references the unit-value schema
- it inherits properties and requirements
- adds a restriction on the unit property via a value set, i.e.,
 - the unit element must be among a list of valid units of time
 - the reference section describes how the value set was chosen https://opensource.ieee.org/omh/1752/-/blob/main/schemas/utility/duration-unit-value-1.0.json



Value sets

- a value set can be defined within a schema
- some schemas are just value sets (e.g., body posture https://opensource.ieee.org/omh/1752/-/blob/main/schemas/utility/body-posture-1.0.json
- a value set is an array of possible values (enumerated list)
- the reference section describes how the value set was chosen
- data must include one of the allowed values to be compliant
- may be exhaustive or not (in which case they can be expanded)



P1752 Schemas

DO

- Define format
- Define properties (required or optional)
- May define value sets for some properties

Example Fragment of Schema (illustrative)

```
"properties": {
    "blood_glucose_range_low_value": {
        "$ref": "#/definitions/blood_glucose_value"
    },
    "blood_glucose_range_high_value": {
        "$ref": "#/definitions/blood_glucose_value"
    }
},
"required": ["blood_glucose_range_low_value",
    "blood_glucose_range_high_value"]
```

DON'T DO

- Don't define value sets for *all* properties
- Don't define value ranges for all properties
- P1752 WG does not define clinical standards

Example Instance

```
{
    "blood_glucose_range_low_value": {
        "unit": "mg/dL",
        "value": 70
    },
    "blood_glucose_range_high_value": {
        "unit": "mg/dL",
        "value": 180
    }
}
```

Metadata

- Metadata is modeled in the header schema
- Header complies with header schema
 https://opensource.ieee.org/omh/1752/-/blob/main/schemas/metadata/header-1.0.json
- Header includes references to information such as details of the measuring solution, algorithm, modality, study protocol
- "Minimum" metadata



Summary of Action Items

Future Meetings

Upcoming Meetings

- P1752.2 WG call
 - Tuesday October 25 at 8 am Pacific
- Cardio-respiratory subgroup:
 - Thursday September 29 at 8 am Pacific
- Metabolic subgroup:
 - Tuesday September 20 at 8 am Pacific



Adjournment