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 meetings and sending a request. Accommodation can be made for special circumstances, which should be brought to the Chair’s attention.
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.
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
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.

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
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

- IEEE SA Best Practices for IEEE Standards Development

- Distribution of Draft Standards (see 6.1.3 of the SASB Operations Manual)
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](http://www.ieee.org/about/corporate/governance)

Approved by SASB in June 2019
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

Approved by SASB in June 2019
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

Approved by SASB in June 2019
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 26\textsuperscript{th} and February 23\textsuperscript{rd}, 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 $\rightarrow$ Health $\rightarrow$ Aging & “pre”-disease $\rightarrow$ Disease
  - Optimize granularity
    - Enable common metrics relied upon in health care delivery, or otherwise allow for extensibility
    - Aspirational: Accommodate (\textit{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) ... \textit{Daylight Savings Time}

Information posted at: https://sagroups.ieee.org/1752/cardio-respiratory-subgroup/
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
  o Blood glucose
  o Blood glucose unit-value (mg/dL, mmol/L)
  o Blood glucose thresholds (cut-off values for low, very low, high and very high)
  o Time in range [TIR], above range [TAR], below range [TBR] addendum proposed today

• Contextual measures
  o CGM
    o percent_time_sensor_active
    o number_of_days_device_worn
  o SMBG
    o number_of_readings
    o average_readings_per_day
Proposed P1752.2 Blood Glucose Schemas

• Initial set of measures (part 2)
  o Blood glucose management indicator (GMI) for CGM
  o Blood glucose variability as coefficient of variation (CV)
  o Ambulatory Glucose Profile for CGM
  o Ambulatory Glucose Profile for SMBG
Ambulatory Glucose Profile CGM - v5.0

AGP Report: Continuous Glucose Monitoring

Goals for Type 1 and Type 2 Diabetes

- Very High: 31% (Goal: ≤5%)
- High: 25% (Goal: <25%)
- Target: 36% (Goal: ≥70%)
- Low: 4% (Goal: ≤4%)
- Very Low: 4% (Goal: <1%)

Each 1% time in range = about 15 minutes

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)**

<table>
<thead>
<tr>
<th>Name</th>
<th>MRN</th>
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**AGP Report**

<table>
<thead>
<tr>
<th>GLUCOSE STATISTICS AND TARGETS</th>
<th></th>
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<tbody>
<tr>
<td>26 Feb 2019 - 10 Mar 2019</td>
<td>13 days</td>
</tr>
<tr>
<td>% Time CGM is Active</td>
<td>99.9%</td>
</tr>
</tbody>
</table>

**Glucose Ranges**

- **Target Range** 70-180 mg/dL
- **Less than 1%** (14min)
- **Less than 4%** (58min)
- **Greater than 70%** (16h 48min)

**Time in Ranges**

- **Very High** (>250 mg/dL) **20%** (4h 48min)
- **High** (181-250 mg/dL) **23%** (5h 31min)
- **Target Range** (70-180 mg/dL) **47%** (11h 17min)
- **Low** (54-69 mg/dL) **4%** (58min)
- **Very Low** (<54 mg/dL) **6%** (1h 26min)

**Average Glucose** 173 mg/dL

**Glucose Management Indicator (GMI)** 7.6%

**Glucose Variability** 49.5%

Defined as percent coefficient of variation (%CV); target ≤36%
Ambulatory Glucose Profile SMBG - v5.0

AGP Report: Blood Glucose Monitoring

Percent BGM Readings in Ranges

- Very High: 12%
- High: 25%
- Target: 58%
- Low: 4%
- Very Low: 1%

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
  - Average After-Meal Glucose: Unable to Calculate
- Lowest/Highest Glucose: 43/354 mg/dL

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

Added in v5.0
Ambulatory Glucose Profile SMBG (older version)

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