Standards Roadmap: Neurotechnologies for Brain-Machine Interfacing
IC17-007 - IEEE SA Industry Connections Activity
26 May 2020

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IC07-007: NeuroTechnologies for BMI

Multi-stakeholder, pre-standardization effort

Goals:

• Overview standards activities related to BMI-related neurotechnologies

• Identify gaps and propose actions

• Engage with the community and promote development of standards

Created 2007, 91 people in shared working space
Neurotechnologies: A tale of diversity

Discrimination power (Fisher score for separating error-related brain activity and correct-related brain activity) of brain connectivity patterns between four brain sources, i.e., frontocentral, left/right frontolateral and centroparietal regions in theta and beta bands. The source level brain activity is estimated by beamforming, and the brain connectivity is estimated by Directed Transfer Function. The Fisher scores are indicated by the darkness of the arrows. Difference of the power spectrum density, error - correct, is indicated by the color of the brain sources.
Neurotech: A growing, evolving ecosystem...

- BMIs are composed of multiple sub-systems for:
  - data acquisition | processing | actuation | feedback

- Interoperability becomes crucial while fulfilling requirements for
  - reliability | safety | communication |
  - regulatory processes | biocompatibility | privacy

- Comprises **clinical** and **consumer** applications
  - Researchers, developers and innovators can exploit mutual synergies
  - Need to balance potential risks

... needs for **standards** in the field
Roadmap public link: 
http://t.co/kvbu8tm5p7?amp=1

Released on Feb 24th. Available in:
- IEEE SA, IEEE Brain, IEEEXplore

Significant visibility in social media at launching time

Initial positive response

Need to reactivate engagement and call for feedback
STANDARDS ROADMAP: NEUROTECHNOLOGIES FOR BRAIN-MACHINE INTERFACING

IEEE SA Industry Connections Activity No. IC17-007

Sensing Technologies
EEG, fNIRS, ECoG, Intracranial, ...

Data Representation, Storing and Sharing
Data storage, data annotation, cybersecurity, ...

Performance Assessment and Benchmarking
Decoding accuracy, sensitivity, specificity, reliability, ...

End-effectors: Actuators and Feedback
NMES, Prosthetics, Exoskeletons, VR/AR Neurostimulation, ...

User Needs
Clinical effect, ergonomics, human factors, portability, safety, privacy, ...
Do you think of standardization as more of a hindrance or promoter in the development of new technologies?

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety</td>
<td>9 (10.8%)</td>
</tr>
<tr>
<td>Terminology &amp; Specs</td>
<td>2 (2.4%)</td>
</tr>
<tr>
<td>Data Ownership</td>
<td>20 (24.1%)</td>
</tr>
<tr>
<td>Cybersecurity &amp; Privacy</td>
<td>12 (14.5%)</td>
</tr>
<tr>
<td>Performance assessment/Benchmarking</td>
<td>39 (47%)</td>
</tr>
<tr>
<td>Data representation</td>
<td>10 (12.0%)</td>
</tr>
<tr>
<td>Neuroethics</td>
<td>25 (30.1%)</td>
</tr>
<tr>
<td>Neurostimulation</td>
<td>21 (25.3%)</td>
</tr>
<tr>
<td>User requirements</td>
<td>25 (30.1%)</td>
</tr>
<tr>
<td>Consumer level neurotech</td>
<td>2 (2.4%)</td>
</tr>
<tr>
<td>Rehab robots/Exoskeletons</td>
<td>25 (30.1%)</td>
</tr>
<tr>
<td>Dual Use</td>
<td>25 (30.1%)</td>
</tr>
<tr>
<td>Augmented Virtual/Reality</td>
<td>10 (12.0%)</td>
</tr>
</tbody>
</table>

How familiar are you with the process for developing a standard?

<table>
<thead>
<tr>
<th>Familiarity</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>25 (30.1%)</td>
</tr>
<tr>
<td>Very low</td>
<td>25 (30.1%)</td>
</tr>
<tr>
<td>Low</td>
<td>25 (30.1%)</td>
</tr>
<tr>
<td>Medium</td>
<td>10 (12.0%)</td>
</tr>
<tr>
<td>High</td>
<td>2 (2.4%)</td>
</tr>
<tr>
<td>Very High</td>
<td>10 (12.0%)</td>
</tr>
</tbody>
</table>

Public perception - Standardization Priorities
## Status and priorities

<table>
<thead>
<tr>
<th>Sensor Technology</th>
<th>End-Effectors</th>
<th>Data management</th>
<th>User requirements</th>
<th>Performance Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current situation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Established standards for electromagnetic safety, biocompatibility</td>
<td>Electrical/Mechanical safety</td>
<td>Cybersecurity standards (non-BMI specific)</td>
<td>Human factors (seldom integrated in BMI design)</td>
<td>Community driven standards (focus on neural decoding)</td>
</tr>
<tr>
<td></td>
<td>Standard lexicon for prosthetics</td>
<td>Community driven standards</td>
<td>Medical design device control</td>
<td>Benchmarking of individual sub-components</td>
</tr>
<tr>
<td></td>
<td>Ongoing development on wearable robotics</td>
<td>EEG consumer devices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level</td>
<td>High</td>
<td>High</td>
<td>Medium/Low</td>
<td>Low</td>
</tr>
<tr>
<td>Standardisation Priorities</td>
<td>Interoperability</td>
<td>Unified Terminology</td>
<td>Cybersecurity/Privacy</td>
<td>User needs healthy and less severely affected patients</td>
</tr>
<tr>
<td></td>
<td>Communication across devices and processes</td>
<td>Interoperability between data mgmnt platforms</td>
<td>Data annotation, Meta data, closed-loop data</td>
<td>User needs (beyond direct user. e.g., caregivers, family)</td>
</tr>
<tr>
<td></td>
<td>Measures of performance, especially when shared control</td>
<td>Interoperability between data mgmnt platforms</td>
<td>Data annotation, Meta data, closed-loop data</td>
<td>Benchmarking of user needs fulfilling</td>
</tr>
</tbody>
</table>
General Recommendations

• Education activities on benefits of standards and their development procedure

• Safety, security and privacy appear as top priorities

• Need for standards on BMI specification and benchmarking

• BMI researchers should be involved in developing standards for related technology (e.g. robotics, VR/AR)

• Synergies between consumer and clinical applications should be supported by complementary standards

• Need for flexible and consistence governance frameworks ranging from good practices, soft law, standards and regulation
Outcomes

• Standards roadmap
• Generated three IEEE SA Working groups
  • WG P2725.1: Standard for Microwave Structural, Vascular or Functional Medical Imaging Device Safety (Chair: Joel Libove, Furaxa)
  • WG 2794: Reporting of In Vivo Neural Interface Research (Chair: Zach McKinney, Scuola Sant’Anna)
  • WG P2731: Standard for a Unified Terminology for Brain-Computer Interfaces (Chair: Luigi Bianchi, U. Roma)

EVENT PARTICIPATION
• IEEE EMBS conference, 2017-2019; IEEE SMC 2017-2019
• International BCI meeting, 2018; Graz BCI conference, 2019

COLLABORATION WITH OTHER ORGANIZATIONS
• OECD Workshop on responsible innovation for health and well-being, 2018
  Led to an OECD working paper and recommendation to member governments
• World Intellectual Property Organization (WIPO) request for input on assistive technologies
Follow-up activities

PUBLICATIONS
• Upcoming article in IEEE Brain eNewsletter
• Opinion paper. Task leader: Pepe Contreras Vidal (U Houston)

EVENTS
• Workshop Global Perspectives on Responsible Artificial Intelligence, Germany, June 2020
• Special session, COMPSAC 2020 – IEEE Computer Society, Madrid, July
• 1st IEEE International Conference on Human-Machine Systems, Rome, Sept 2020
• Workshop “Standards for Neurotechnologies: Strategic Vision2025” at EMBC 2020. CANCELLED
• Workshop on Benchmarking Standards for BMI, Int. BCI Meeting, Brussels, 9 June 2020 POSTPONED 2021

CALL FOR INPUT ON ROADMAP
• Extended to Sep 30th 2020
• Need for input for a more diverse group in order to refine the roadmap and inspire further standardization activities
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