Blackrock Microsystems

Standardization in BCI
- initial thoughts -

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A. Who is the “customer”
B. BCI system components and structure
C. Key questions

Who is the customer? (Motivation)

- User (industry or end user)
  - Interchangeability / flexibility
  - Reduced cost
- Regulatory oversight / legislation / consumer protection
  - Standards that allow easier evaluation of technologies/devices/systems for safety and efficacy
  - Definition of relevant performance metrics
  - Reduced cost

Structure

BCI system

Implantable vs. external

Hardware	Firmware	Software

Frontend/electrode	Frontend/Amplification	Data acquisition	Data Processing	Effector
• Electrical safety? • Validation of reliable connection?	• Standard output range? • Bandwidth • Voltage range • Gain • Input impedance	• Sampling rate • AD resolution	• Signal/trial/channel org • Physiological event detection • System/app specific algorithms	• Physical interface (connector) • Electrical Stimulation safety standards • Data formats

Potential targets for standardization

- Wireless communications protocols
- Wired communications protocols
- Connectors (implantable vs external)
- Hardware APIs
- Data quality measures for invasive sensors
- Data quality measures for non-invasive sensors
- Data quality measures for effectors
- Control signal bit rates

Potential targets for standardization

- Wireless/wired communications protocols
  - What applications? Research versus clinical/therapeutic
  - What data rates are needed and feasible
  - Acceptable Bit error rate/dropped packets
  - Backup solutions for synchronization/integrity of data
- Wireless
  - Error correction algorithms
  - Multi-Antenna configurations (cell phone/communications based?)

Existing options for standardization

Wired

CEN ISO/IEEE 11073 is mostly used for medical devices (but not necessarily BCI)

Wireless

Wireless Medical Telemetry Service (WMTS)
Medical Device Radiocommunication Service (MedRadio) (including the former Medical Implant Communications Service (MICS))
Medical Micropower Network (MMN)
Medical Body Area Network (MBAN)
Cellular communication chipsets (Wi-Fi and Bluetooth)
RF identification (RFID) products

Note: None of these standards can handle high data rate communication except Wi-Fi, but the cellular chipsets are very high power (~ watts).
Error correction mechanisms required for data integrity
Question of what data is really required

Potential targets for standardization

- Connectors
  - Research (Omnetics, Semtec, ZIF, Cereport, micro USB, mini HDMI, Cereport headpins, custom)
  - Clinical (mostly hard wired connections, Neuroport, etc.)
  - Project needed on development of reliable implantable and reusable connectors with higher lead count
- Hardware APIs
  - System dependent: e.g. Blackrock Central, Plexon offline sorter, Neuralynx Cheetah, Matlab, NI Labview, custom APIs, etc.

Potential targets for standardization

- Data quality measures for invasive sensors
- Data quality measures for non-invasive sensors

Depends on the device communication standards, which have different communication protocols (HL7, RS-232, Bluetooth, Wi-Fi)
Bit error rate (BER) as common metric?

Research vs. Clinical?

Potential targets for standardization

- Control signal bit rates

Wired: signal logic family (ECL, PECL, LVDS, TTL, CMOS, …), shielding

Wireless: Signal to noise ratio (SNR), modulation schemes (OFDM,QAM, FSK, OOK, FM, AM,…) , encoding (Manchester, 8b/10b, 5b/6b, forward error correction, Hamming…)

Most BCIs are wired, they rely on their signal logic family and shielding to ensure the signal quality. Wireless BCIs are rare at the moment, and rely mostly on the SNR/modulation scheme to ensure its quality.

Discussion

A few potential next steps/talking points

- Early stage industry (premature) – but right time to start discussion
- Identify existing “quasi “ standards as starting point for pilot standardization
- Learn from previous efforts towards standardization in MEMS/Microsensors
- Define Standards where possible, at interfaces, allow freedom/flexibility wrt sensor / electrode / electronics design
- Role of 10993 and ISO 60601
- What are acceptable performance metrics for electrodes (impedance, at what frequency, encapsulation quality, SNR, time dependency/robustness, etc.) and do they need to be defined or do we just define the interface to electronics?