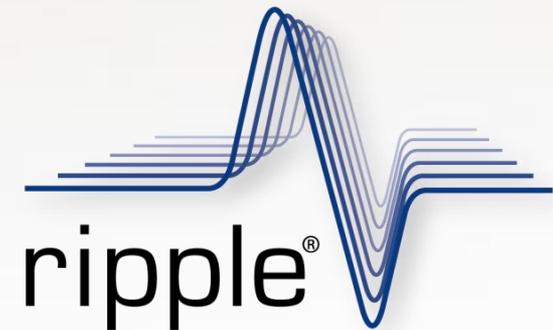


# **NIH Workshop on Standards and Modularity of Brain-Computer Interfaces and Neuroprostheses**

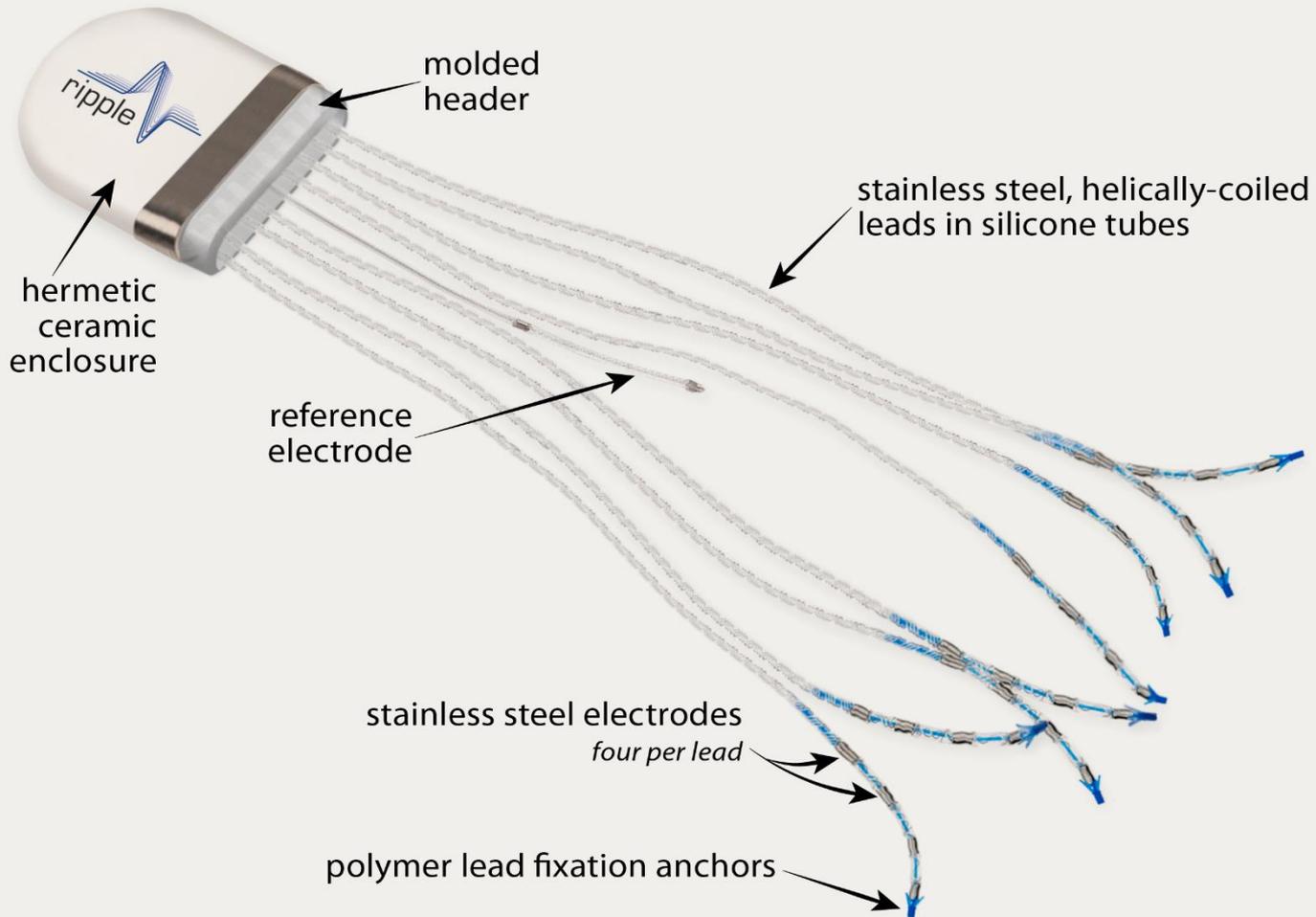
30 June 2016  
Dan Merrill  
Chief Clinical Scientist  
Ripple LLC



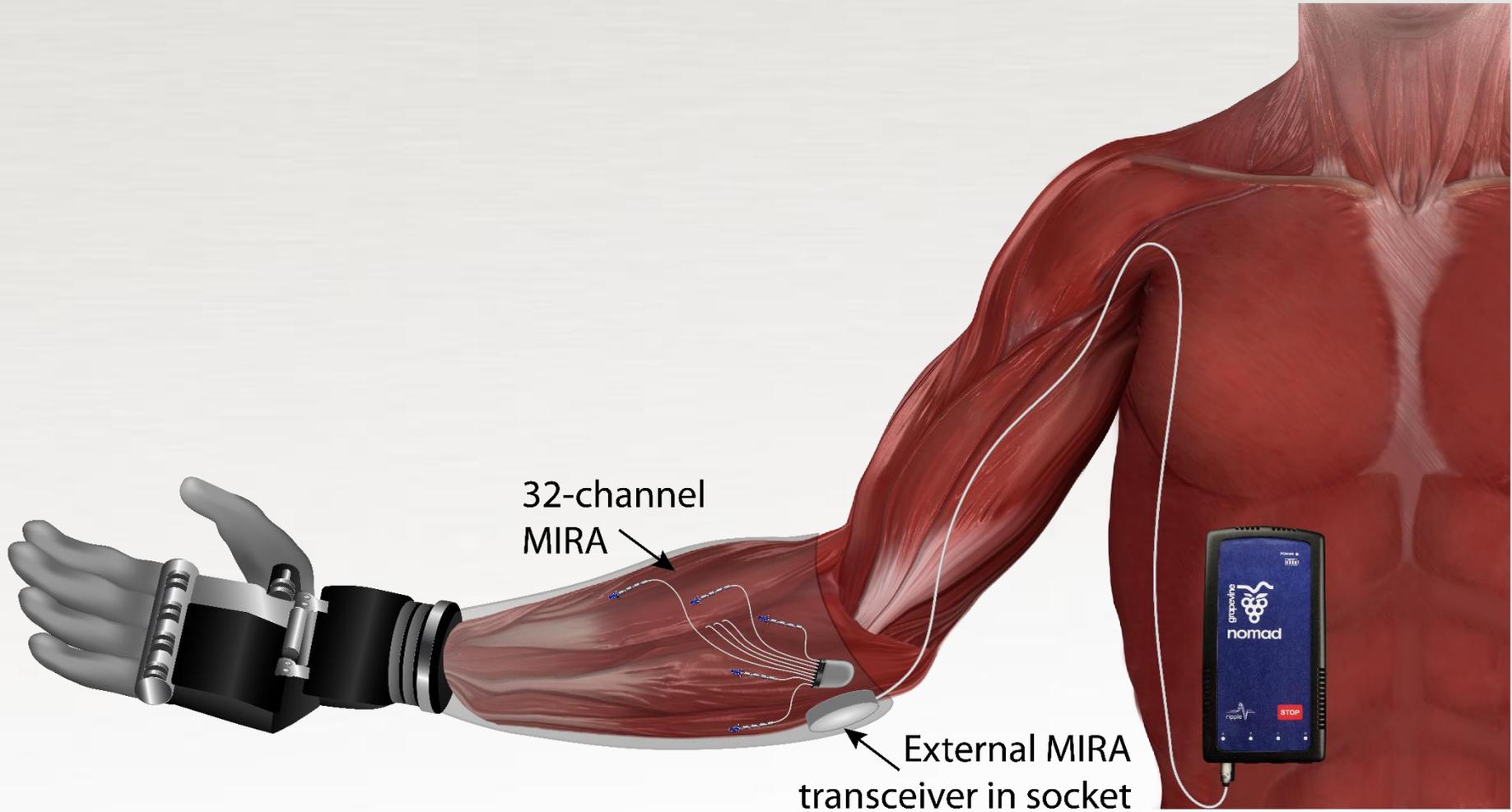
# Disclosure

- DRM is an employee of Ripple LLC, a for-profit neurotechnology company, developing neuroprosthetic devices discussed herein
- I will use these systems to illustrate a potential evolution of product design, and milestones where standardization and modularity are relevant

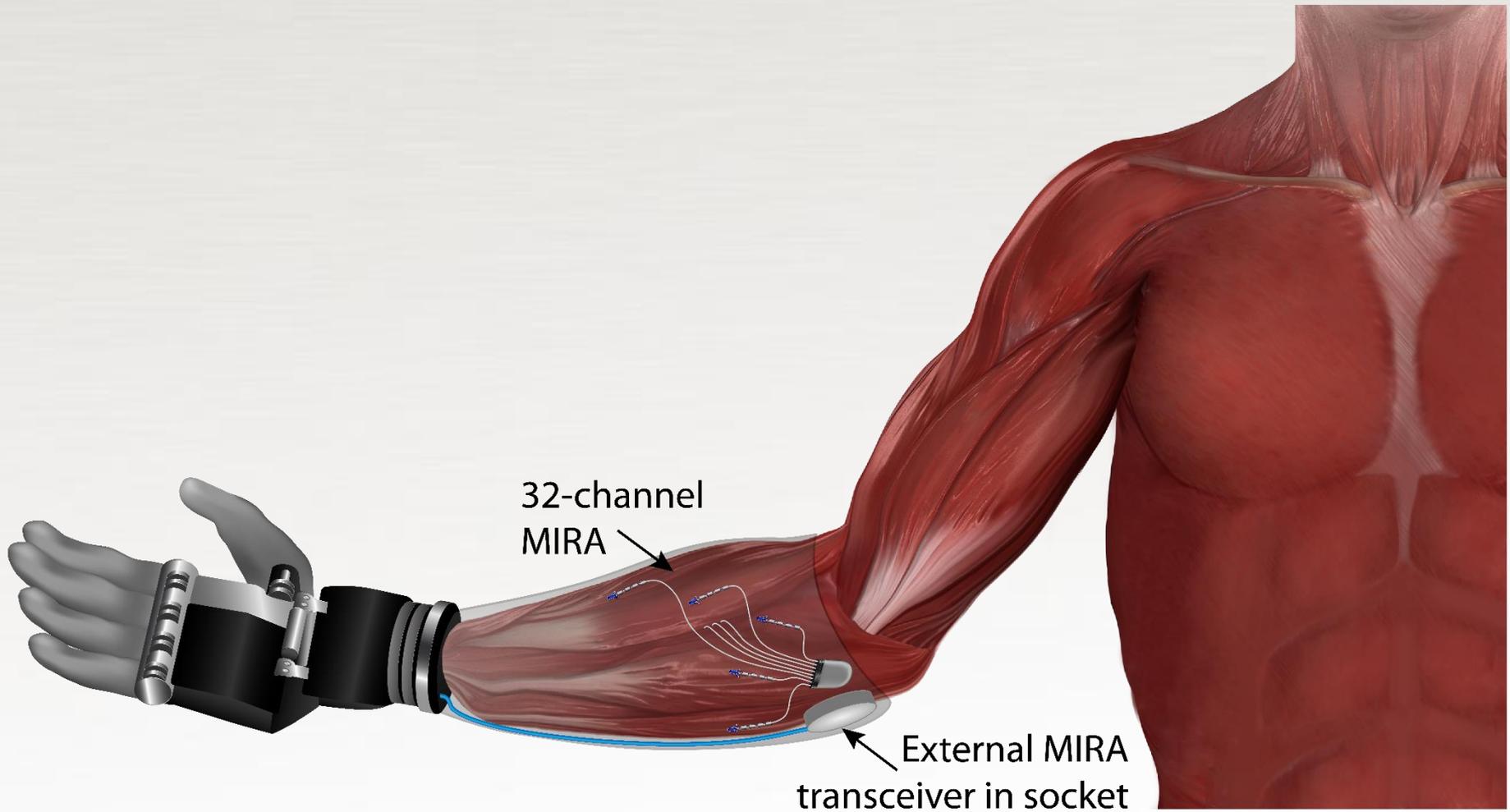
# Myoelectric Implantable Recording Array (MIRA)



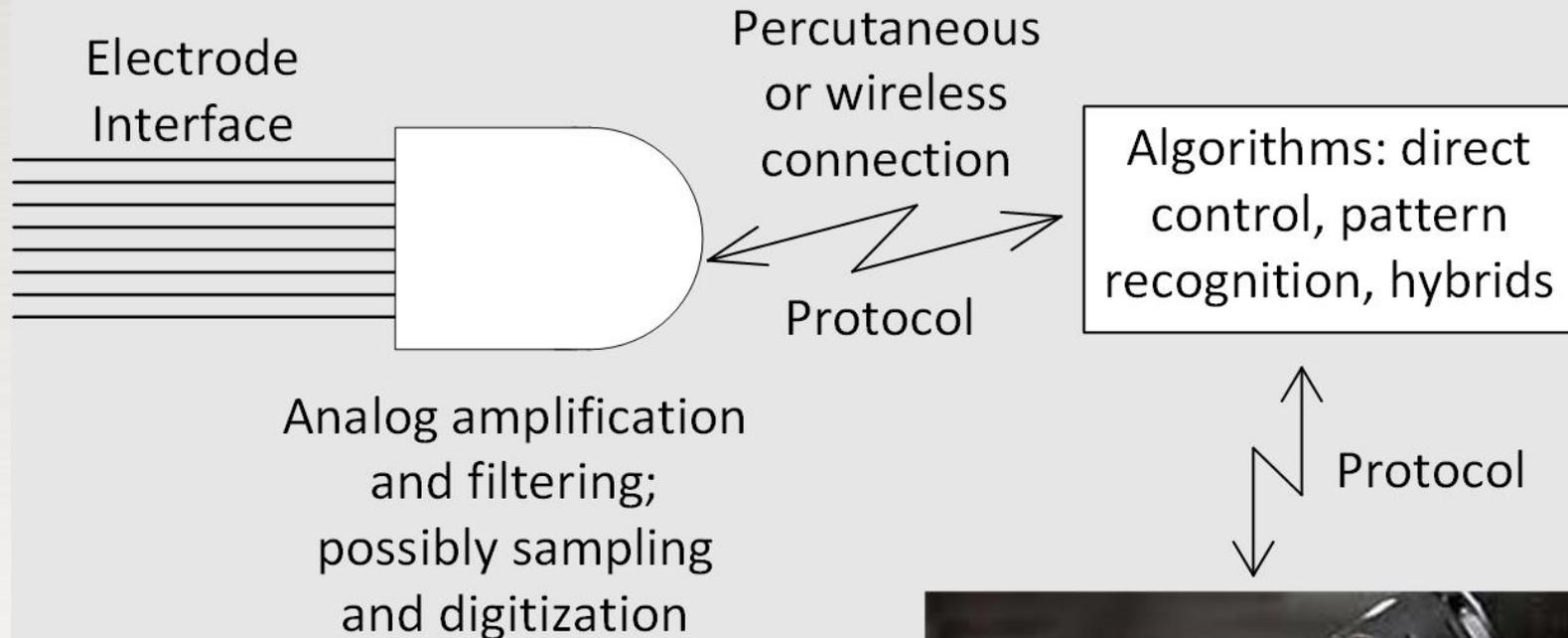
# HAPTIX System



# Market System



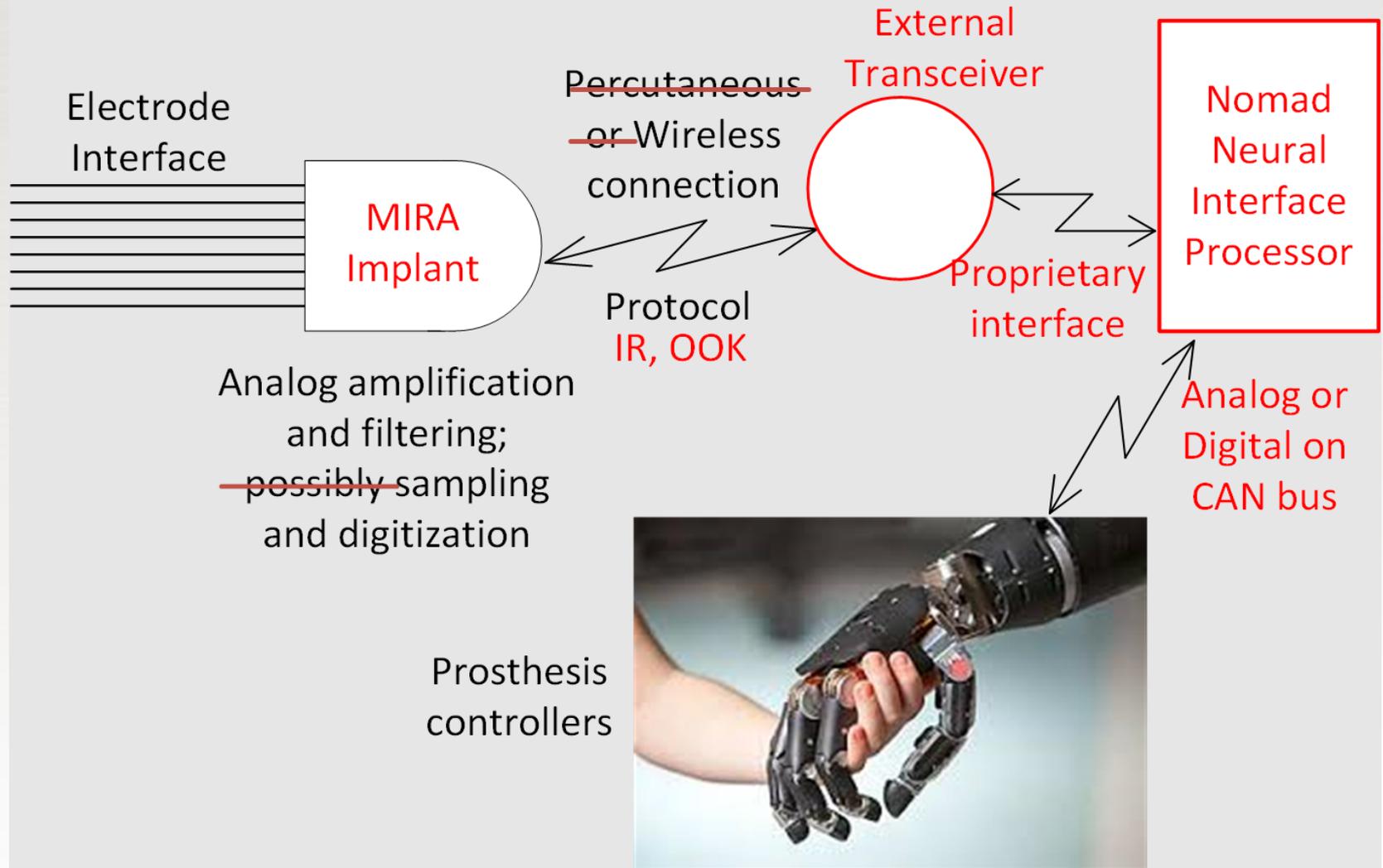
# Building Blocks



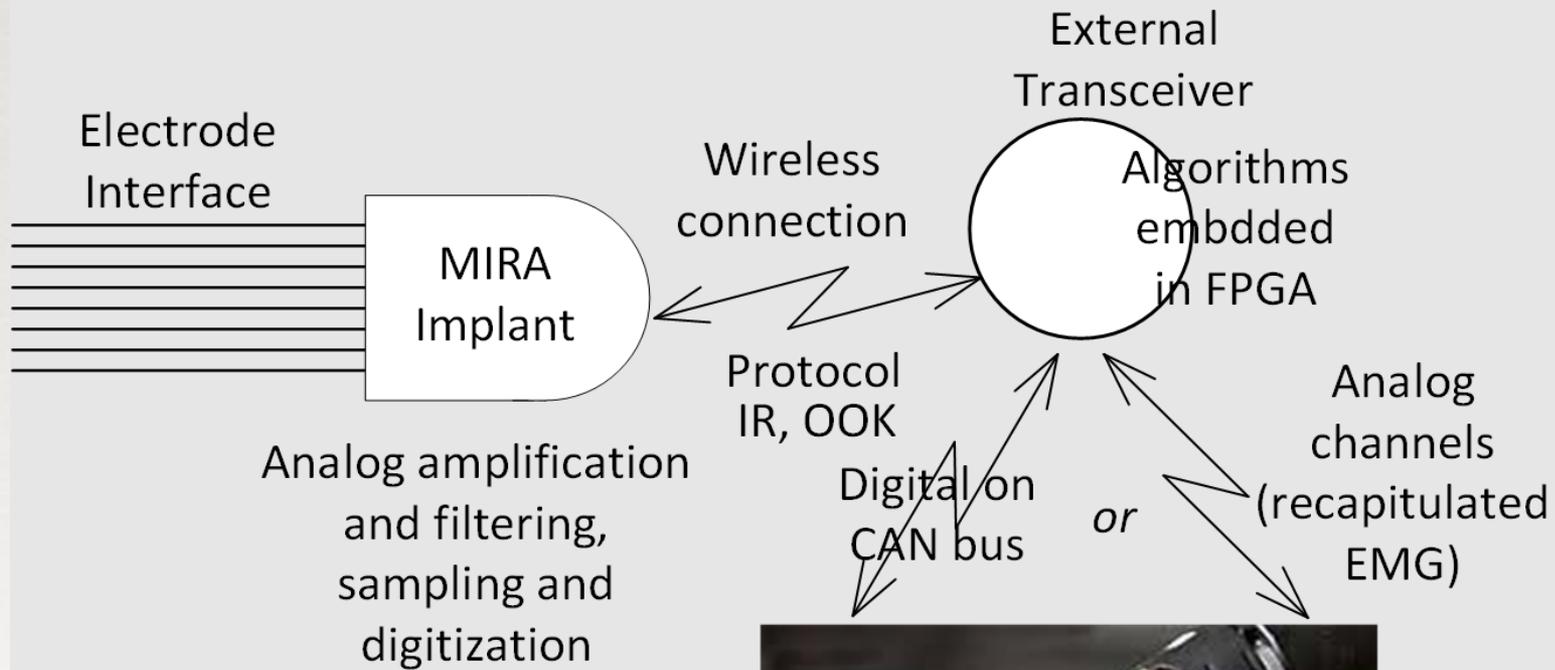
Prosthesis controllers



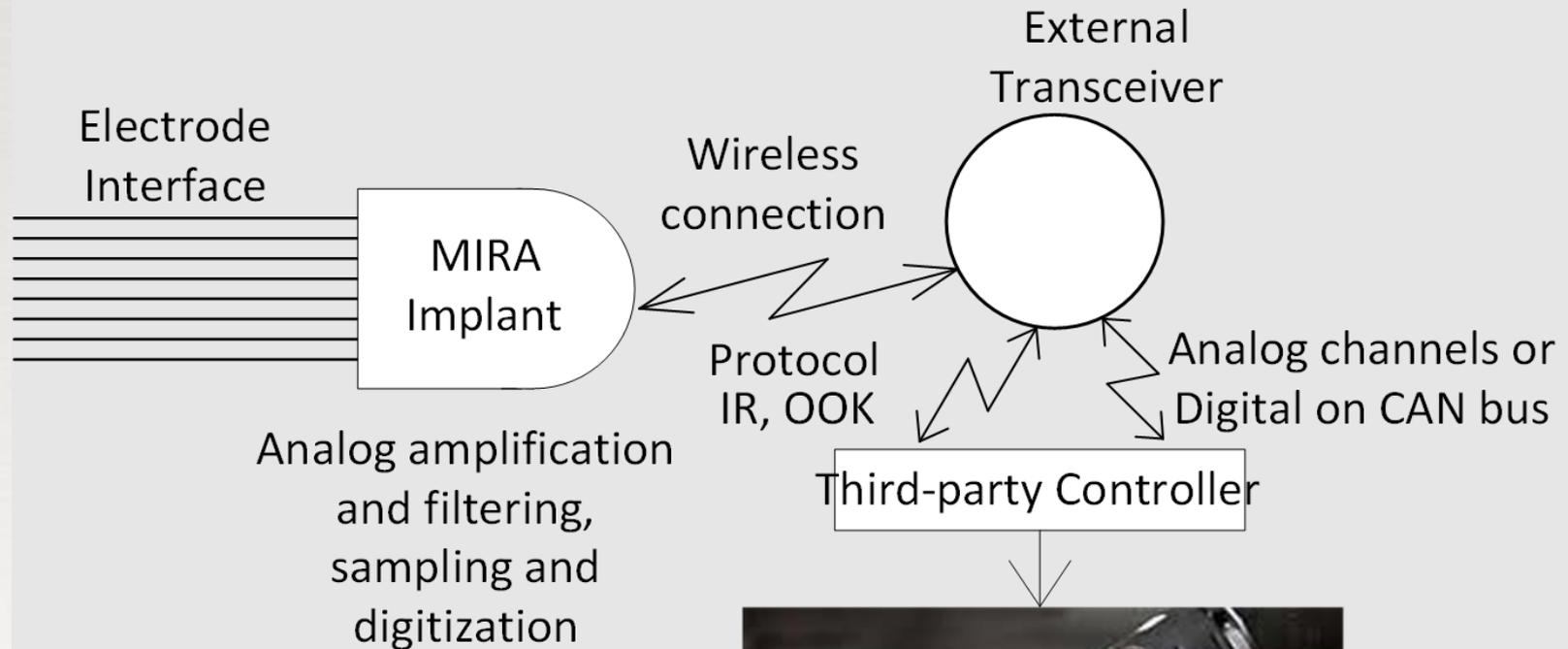
# HAPTIX Pilot Study System



# Market System



# Market System Option



Prosthesis controllers



# Interface Standards

What needs to be defined?

- For wireless data transfer:
  - Carrier
  - Modulation scheme
  - Relevant emissions regulations
- For wired data transfer:
  - Number and definition of each line
  - Data encoding scheme
- Handshaking protocols
- Mechanical interface

# Why Should We Care?

- Small community with similar motivations
- Can't afford schedule, costs, and delayed benefits incurred by designing interfaces in a vacuum



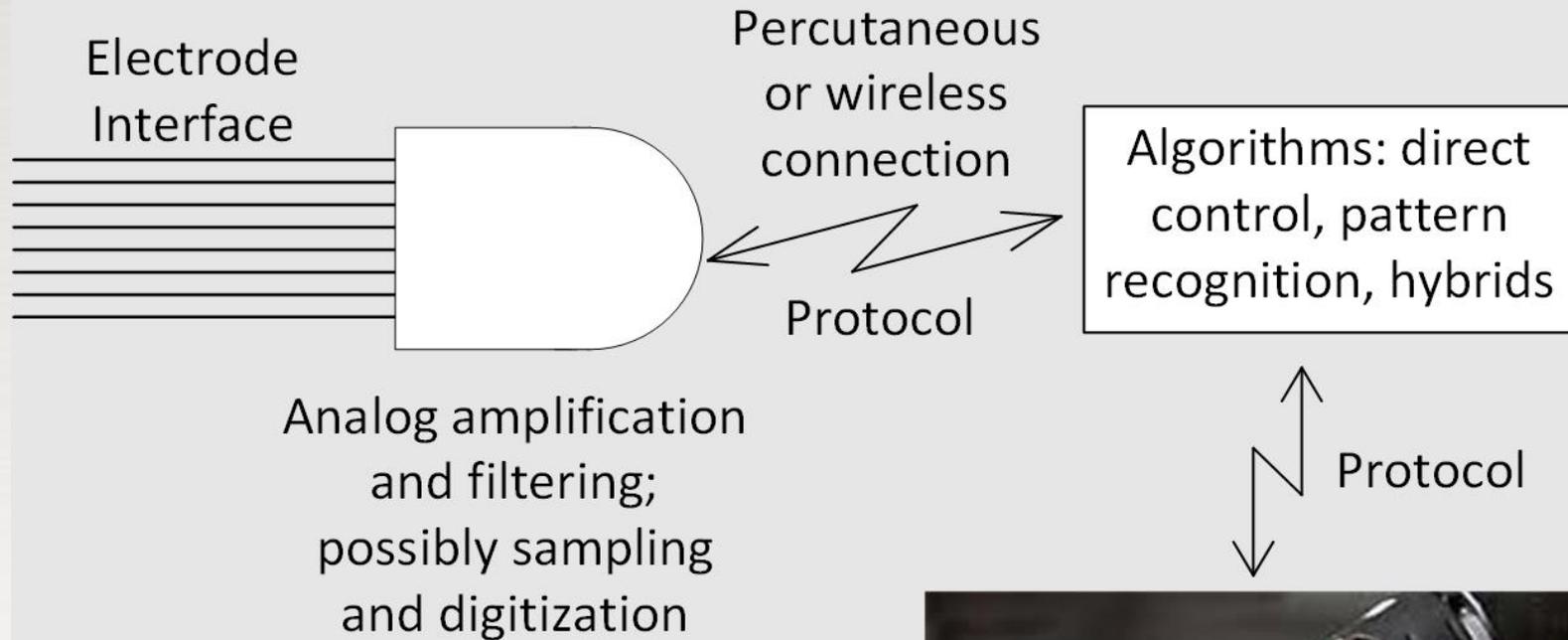
# What Not Standardize?

- Enables the competition?
  - Market is too small to develop end-to-end in a vacuum
- Stifles innovation?
  - All the more reason to form consensus – develop reasonable constraints which enable interoperability
- Optimization process
  - Multiple conflicting parameters – which ones really matter? Do I sacrifice per channel sampling rate to get many channels?
  - Need to specify enough, without becoming exclusive. Can we capture +/- one sigma on all parameters of interest? Is this enough? Do we capture +/- three sigma on one particularly important parameter at the expense of something else?

# The Day is Here

- Adoption of standards by the community (“standardization with a small s”) serves us all
  - Decreased verification and validation effort
  - Decreased regulatory burden
  - Decreased time to market
  - Interoperability prevents exclusion in the market

# Modularity



Prosthesis controllers



# Modularity: Testing for Safety and Effectiveness

- Safety testing: IEC 60601-1, ISO 14708 for implants
- Emissions: IEC 60601-1-2, FCC regulations
- Biocompatibility and sterilization for implants
- Human Factors
- Performance testing
- Hazard Analyses
- Potentially heavy documentation burden
- Multiple regulatory submissions

# Costs and Time for Testing

- Consider one implantable sensor, three processing subsystems, five prostheses
  - 15 rounds of system level testing?!?
- *Enforced testing of all combinations of systems will undermine innovation and translation*
- *The solution is viable interface standards, which subsystems can be tested against*

# Advantages of Modularity

- Advantage to manufacturers:  
Streamlined regulatory review process
- Quicker, less expensive time to market
- Advantage to patients: upgradability –  
no need to replace a system when a  
component is improved

# Conclusions and Recommendations

- Absence of consensus undermines us all, dividing a small market into ever-smaller segments
- The formation of consensus groups can enable us to grow as a community
- The time to start on the small s is now
- Paves the road for big S
- Enforced testing of all system combinations as a whole will effectively crush translation
- We need to work as a community to get regulatory adoption of modular testing