Things to Consider When Developing Electronic Implantable Devices

Presented by

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Veris Health

- **Traditional therapeutic implantable devices have evolved:**
  - Pacemakers
  - Deep brain stimulators
  - Nerve stimulators
- **Expanded opportunities for implantable monitoring beyond cardiac rhythm & glucose**
- **Intelligent surgical implants**
  - Orthopedics
  - Vascular

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Veris Health

- **Clinical benefits:**
  - Automated long-term therapy
  - Longitudinal data
  - Quality of data
  - Patient comfort & adherence
  - Expanded physiologic sensing

- **Clinical challenges:**
  - Data overload
  - New workflow
  - Staffing requirements
  - Proving efficacy
    - Clinical outcomes
    - Health economics

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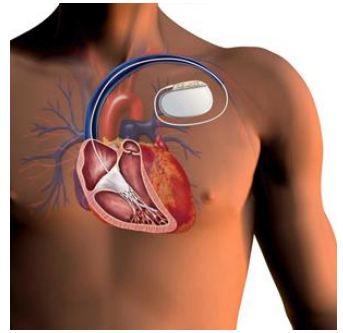
Architectures

- Fully Implanted



- Implanted Portion driven by External Module

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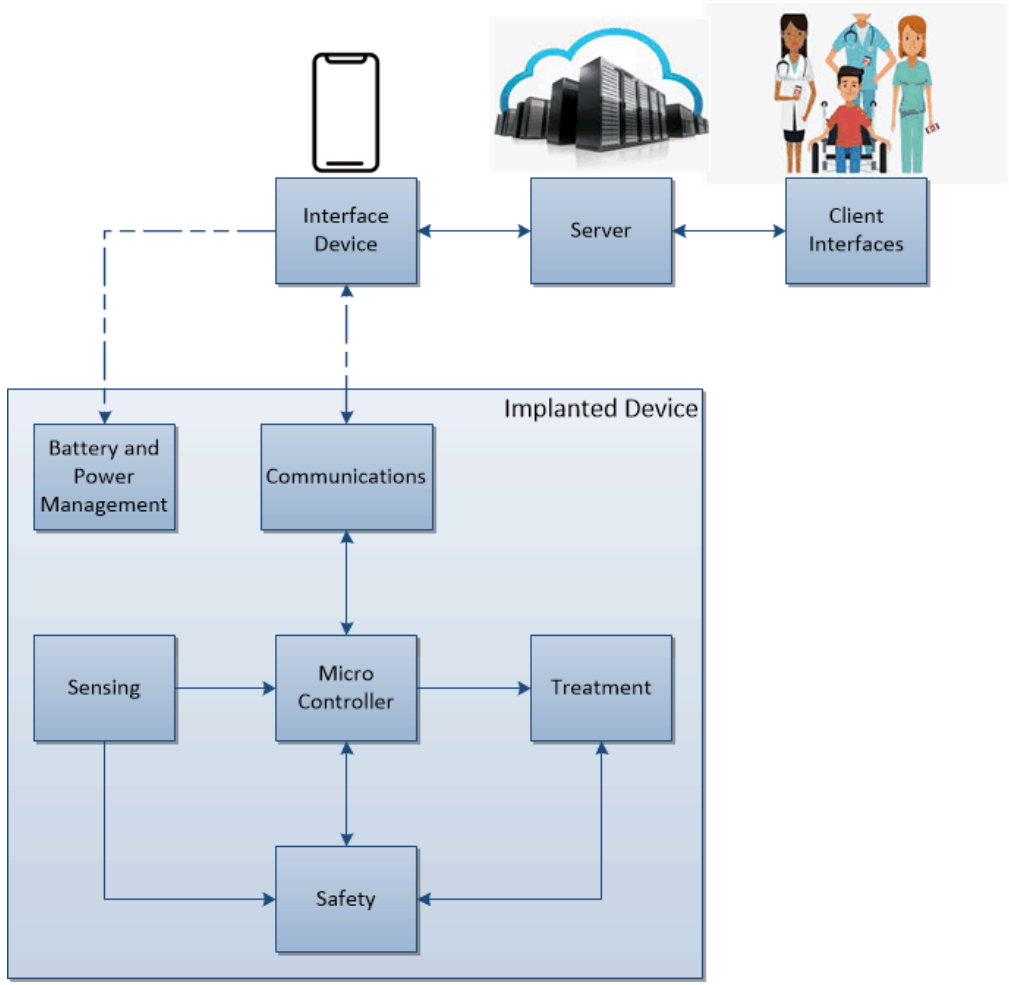
Implantable Architecture



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Architectures

Safety Critical
High Reliability

- Fail Operative vs. Fail Off
- Redundancy vs. Robustness
- Independent Monitoring & Alarming
- Swapping

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Power

Power limitations drives many decisions

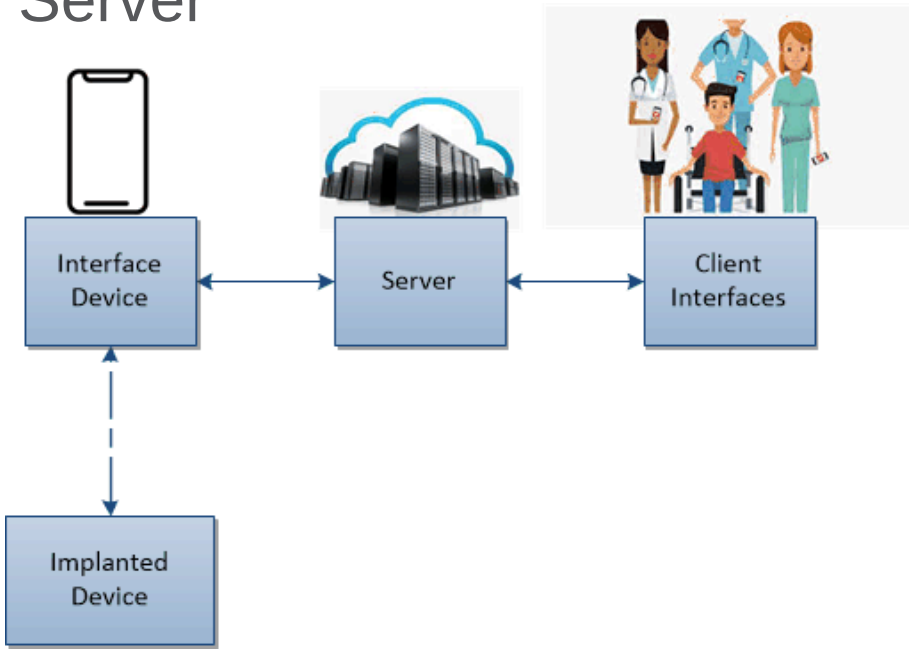
- Feature selection
- Measurement frequency
- Algorithmic complexity
- Sense and drive electronics
- Data storage
- Communications
- ASIC vs. COTS

Power

- Primary Cells
- Rechargeable
  - Transcutaneous charging

Connectivity

- Where to do what?
  - On-Board
  - Interface Device
  - Server



Connectivity

- Depth of Implantation
- Connection Intervals
- Connection Consistency
- Software Security
- Patient Confidentiality

Connectivity

- Ubiquitous User Interfaces
- Data Rates
- Data Quantity
- Implications for Machine Learning

Sensing and Stimulating

- Charge Balancing
- Chemical Sensing
- Many Channels

Takeaways

- Make product tradeoffs wisely
- Minimize to the essentials
- Reduce Power
- Use Connectivity sparingly

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RESOLUTION MEDICAL

Managing the development process

- **Definition of Success**
- **What are the key risks?**
  - Technology
  - Funding
  - Approval Pathway
  - Supply Chain
  - Timing
  - Collaboration
- **Special focus should be given to Interfaces for Risk assessment**
  - Development Partners
  - Sub-system interfaces
    - Electrical
    - Mechanical
  - Design Development Information Management

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Managing the development process

- **User Needs Definition**
- **Who are the Intended Users?**
  - Clinicians
  - Support Staff
  - Patients
- **Other Requirements?**
  - Performance (including Safety)
  - Marketing
  - Regulatory
  - Cost
  - Manufacturability

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RESOLUTION MEDICAL

Design for Excellence (DFx)

- **Definitions**
  - Design for Manufacturing (DFM)
  - Design for Assembly (DFA)
  - Design for Manufacturing and Assembly (DFMA)
  - Other “Design for” modalities –
    - Reliability
    - Quality
    - Supply Chain
    - Testing
    - Maintenance
    - Cost
    - Sustainability
    - Product Life Cycle

- Early & Persistent Review of Manufacturing & Assembly will help mitigate DFx Associated Risk

- Most DFx modalities are included in Design Control Process

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Questions?

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Thank you!

Every Great Project Starts With A Thoughtful Conversation

Contact Us

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