DRAPER

Package Architecture and Component Design for an Implanted Neural Stimulator with Closed Loop Control

Caroline K. Bjune

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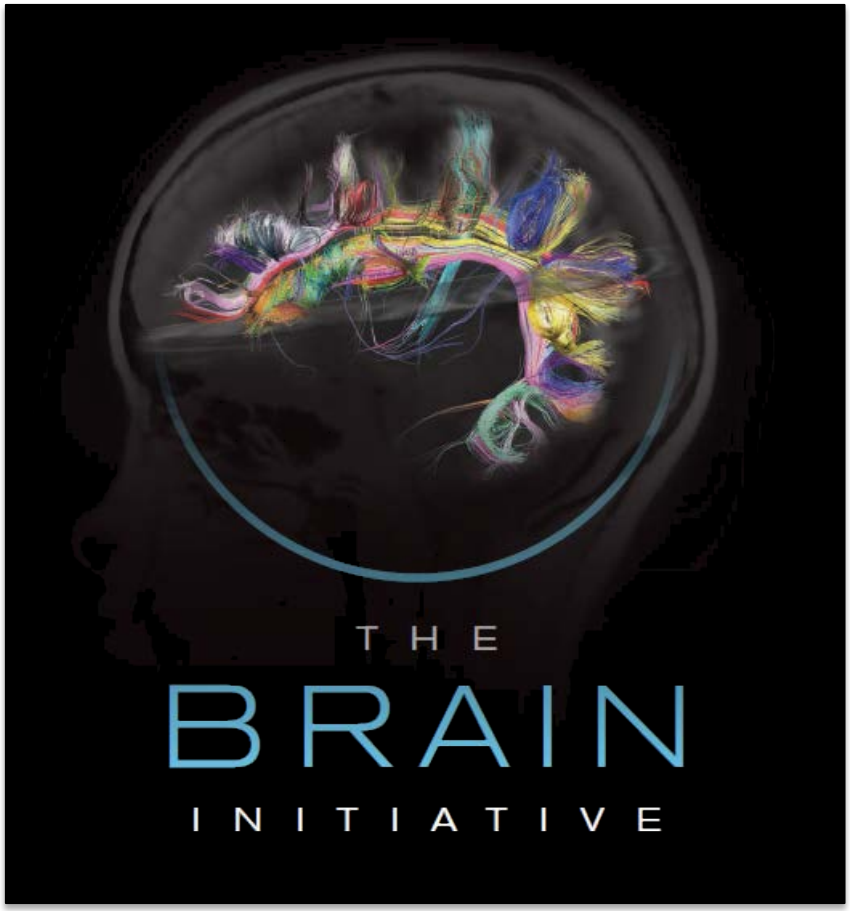


"There is this enormous mystery waiting to be unlocked, and the Brain Initiative will change that by giving scientists the tools they need to get a dynamic picture of the brain in action and better understand how we think and how we learn and how we remember. And that knowledge could be – will be – **TRANSFORMATIVE**."

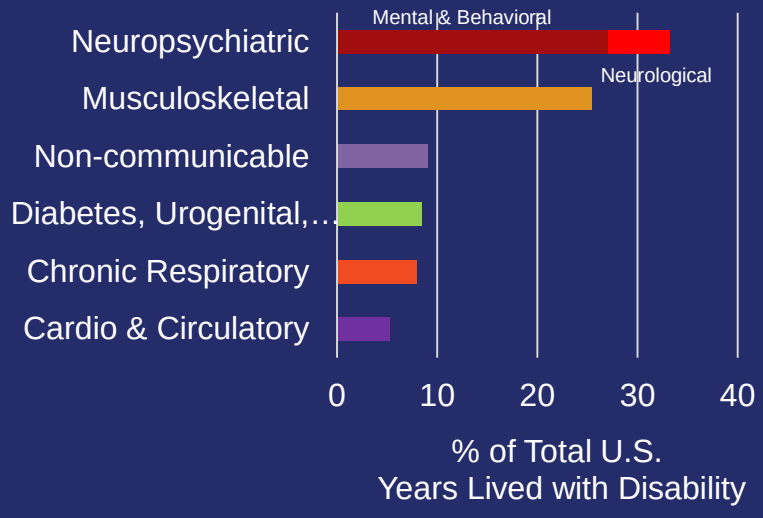
President Barack Obama, April 2, 2013

Social Impact – Why this is Important

- In the 21st century, brain disorders – neurodevelopmental and neurodegenerative – will be the most disabling and most costly chronic diseases
- 20M+ (6.7%) Americans have had a depressive episode in the last 12 months
- 5M+ Americans suffer from Alzheimer's disease costing $200B+/year
- 2.4M+ Americans have schizophrenia, with no fundamentally new drugs from the pharmaceutical industry in over 20 years
- From 2000 through 2011, 235k+ service members diagnosed with traumatic brain injury
- In 2009, 248k+ children (19 or younger) treated for sports and recreation-related concussion or traumatic brain injury

THE BRAIN INITIATIVE HAS ENORMOUS POTENTIAL FOR SOLVING PERSISTENT MYSTERIES OF BRAIN FUNCTION, SPINNING OFF TECHNOLOGIES THAT SEED NEW INDUSTRIES AND OPENING THE DOOR TO NEW TREATMENTS FOR DISEASES AND DISORDERS OF THE NERVOUS SYSTEM

Leading Diseases in U.S. (2010)



Content from NIH NIMH

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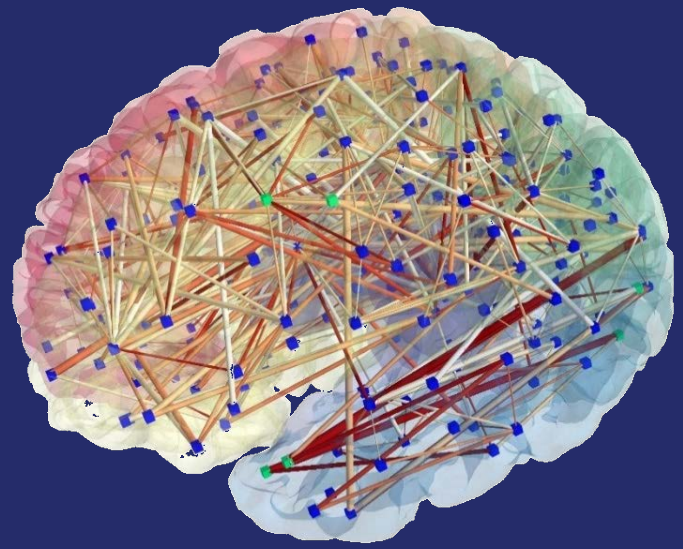
Overview of DARPA SUBNETS

- Develop a new understanding of complex, systems-based disorders of the brain.
- Develop new close-loop therapies for neuropsychiatric and neurologic disease

- TRANSFORM DBS platform:
  - *Senses brain and body's electrical activity*
  - *Correlates that activity to a patient's psychiatric symptoms*
  - *Then delivers electrical stimulation to alleviate those symptoms.*

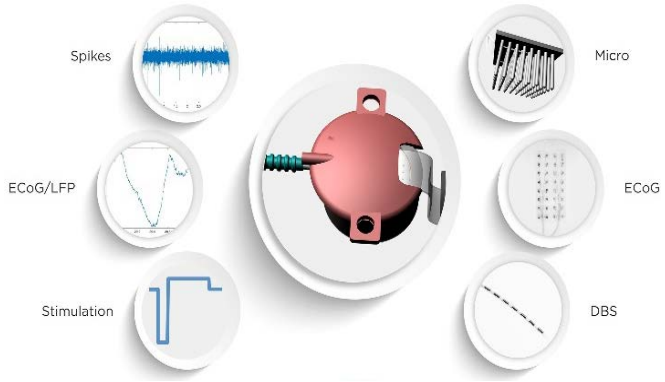
Unlike single-target devices like cochlear implants and pacemakers, achieving this neuropsychiatric therapy requires the ability to record and stimulate in multiple and distributive areas of the brain (cortical and subcortical) – System Based Therapies



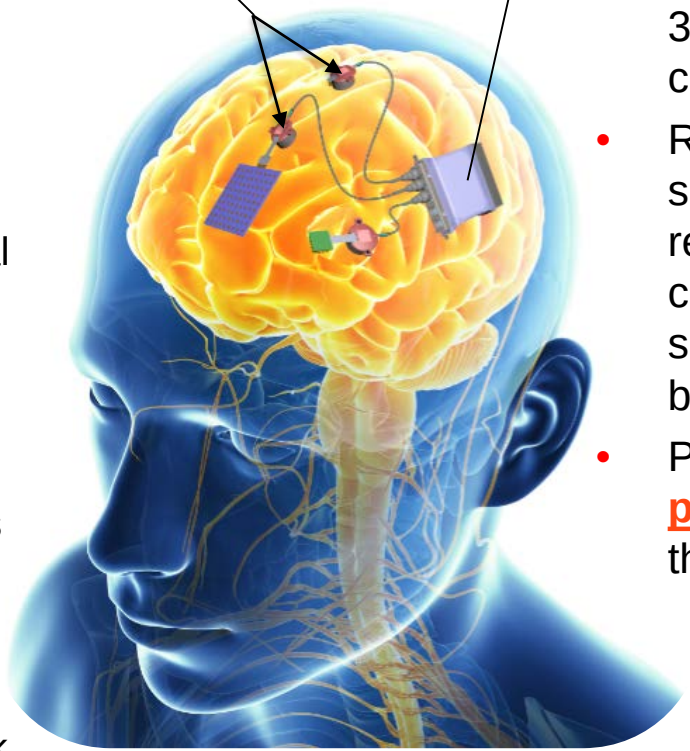
TRANSFORM DBS SYSTEM ARCHITECTURE

PROVIDING ON-DEMAND PATIENT-SPECIFIC CARE TO TREAT NEUROPSYCHIATRIC ILLNESSES

SATELLITE SYSTEM



- Allows for a distributed access to neural sites
- Enables noise-sensitive electronics to be placed in close proximity to neural sites
- Access both spikes and LFP's activities
- Record and stimulation
- Standardized feedthrough interface - Microelectrode arrays, ECoG and DBS electrodes, commercial connector block
- Up to 64 channels per satellite



CENTRAL HUB SYSTEM

- Supports up to 5 satellite systems - enabling up to 320 reconfigurable channels
- Reconfigurable to support new clinical research, and allows clinician to select satellite-electrode system based on patient's needs
- Providing a **customized**, **patient specific** therapeutic system

Cranially mounted, close loop system – consisting of a central hub and multiple satellites

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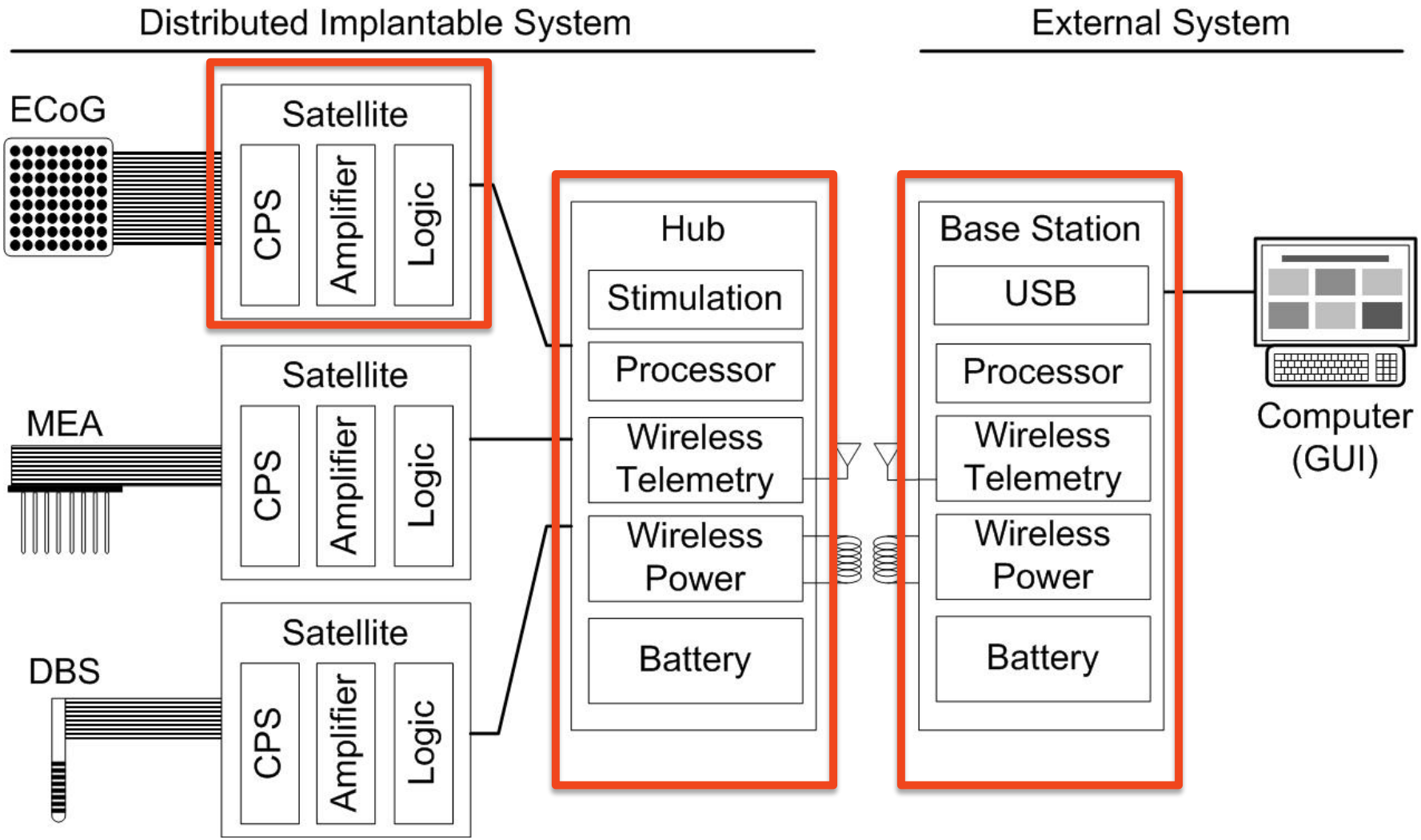
TRANSFORM DBS – System



TRANSFORM DBS SYSTEM

FLEXIBLE PROCESSING ARCHITECTURE ENABLES ADVANCED ALGORITHM DEVELOPMENT

3 MODES OF CLOSED-LOOP PROCESSING

1 Autonomous

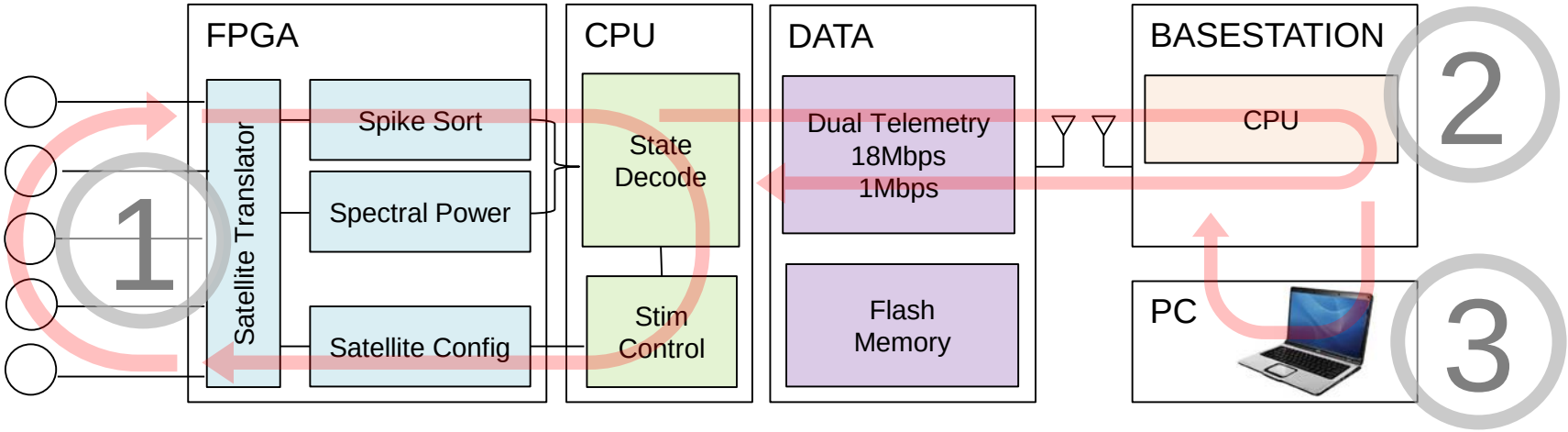
All processing performed within the implanted system for normal daily use

2 Base Boost

Enhanced processing and daily algorithm optimization supported by processing in the base station

3 Computer-in-the-loop

Early algorithm development, data visualization, real-time analysis, and device configuration



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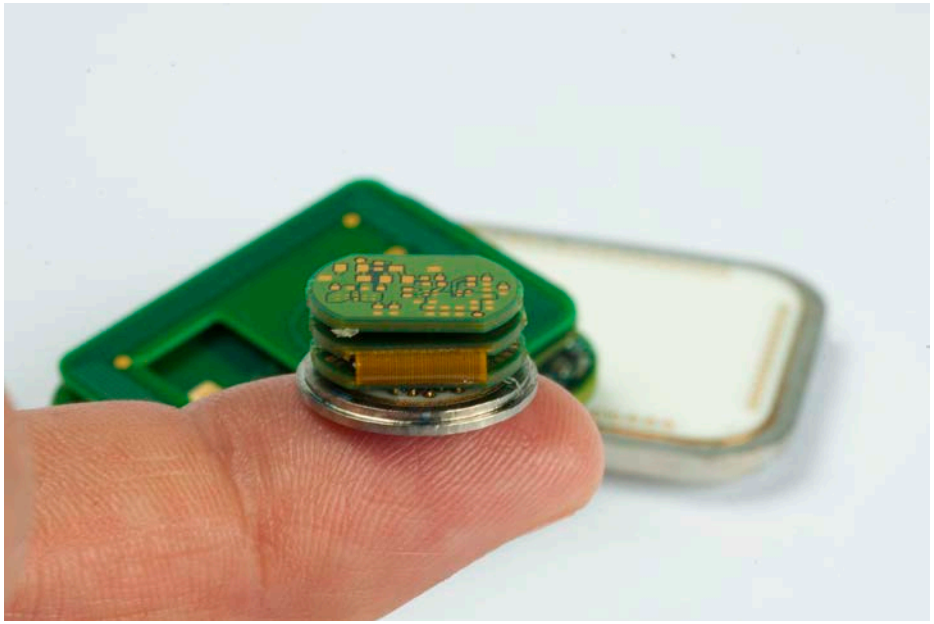
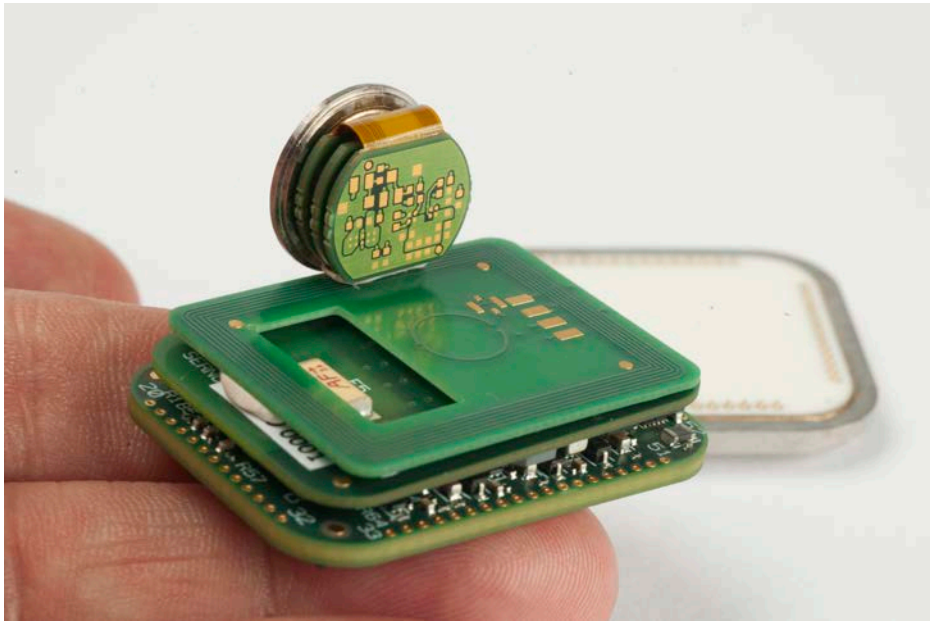
TRANSFORM DBS Phase 1 Systems



Dime size Satellite

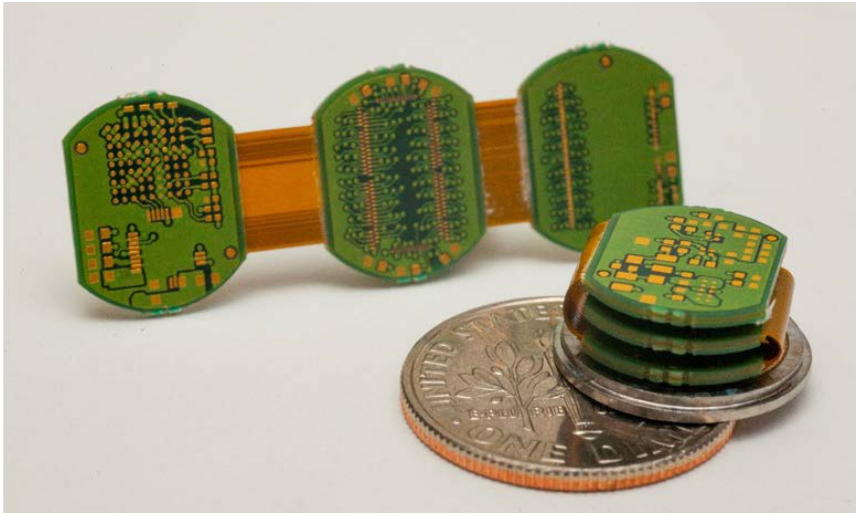


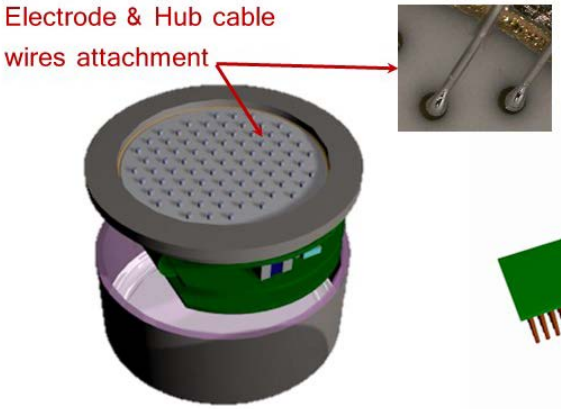
Satellite with Miniaturized Hub Electronics

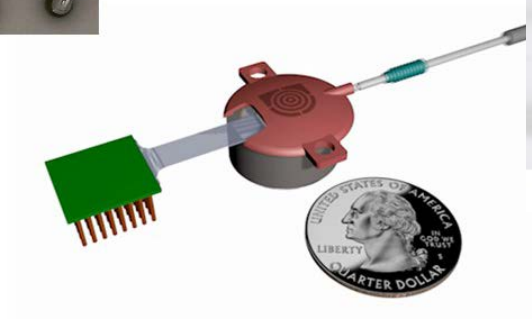
Satellite System

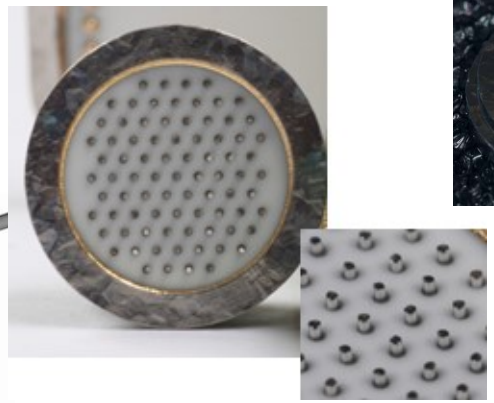
Miniaturized Hermetic Enclosure:

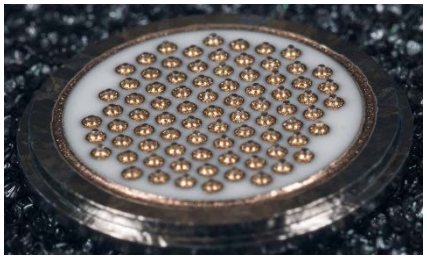
- Designed to fit within a within a 14mm diameter surgical burr hole
- Rigid-flex board – enables folding of electronics
- 81-pin high density ceramic feedthrough plate and titanium enclosure
- Each satellite can accommodate up to 64 channels (electrodes; COTS connectors); connects to hub cable







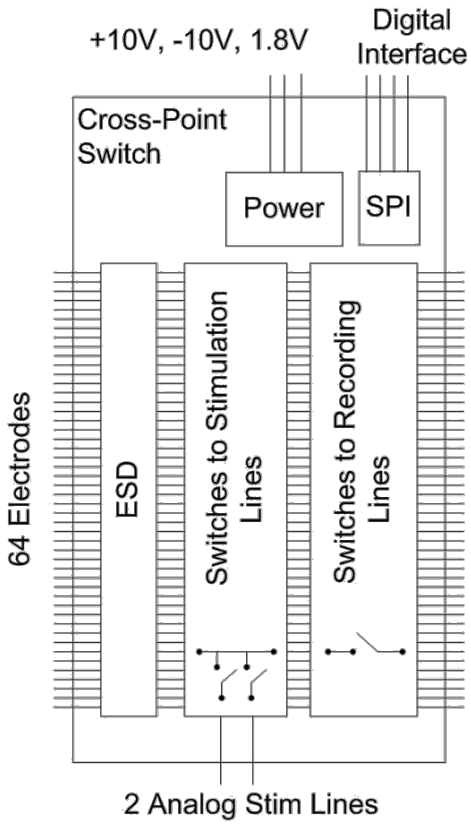


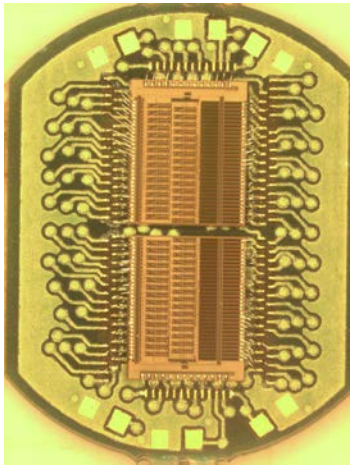


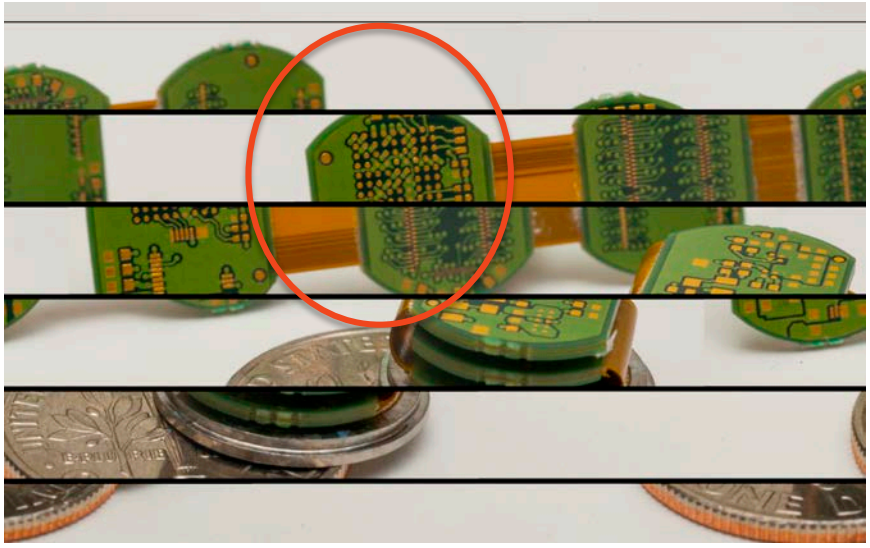
Phase 1 Satellite System: Custom Cross Point Switch Matrix

Custom ASIC

- 64 electrodes
- 2 analog stim inputs
- +/- 9V range
- 3mm x 3.75 mm
- < 500 uW power
- 75 Ω on resistance
- -60 dB isolation
- 8 kV ESD
- <300 pA leakage



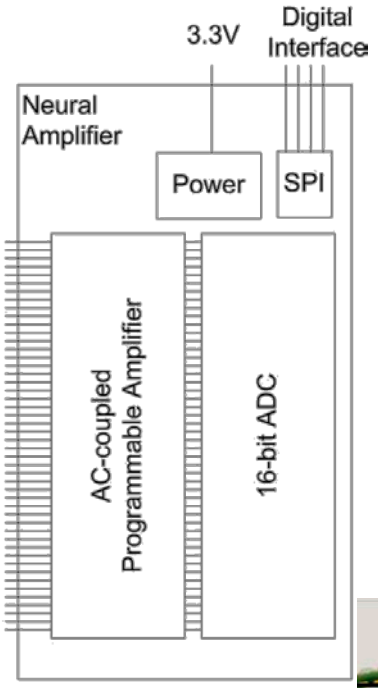


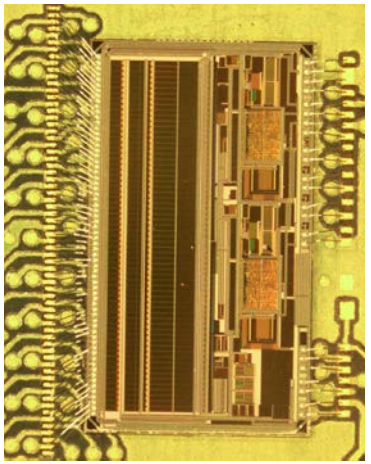


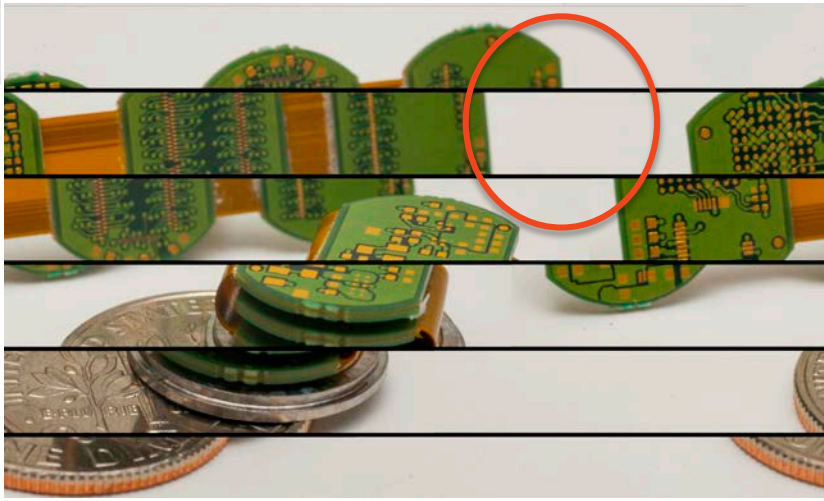
Phase 1 Satellite System: Re-Configurable Amplifier

Amplifier ASIC

- 64 channels
- Integrated 16-bit ADC
- Reprogrammable:
  - *Bandwidth*
  - *Sampling rate*
  - *Channel "sleep"*
- <2.8 uVrms noise(0.5Hz-10kHz)
- Artifact "Fast Settle"
- Impedance measurement
- Monitors temp & supply voltages







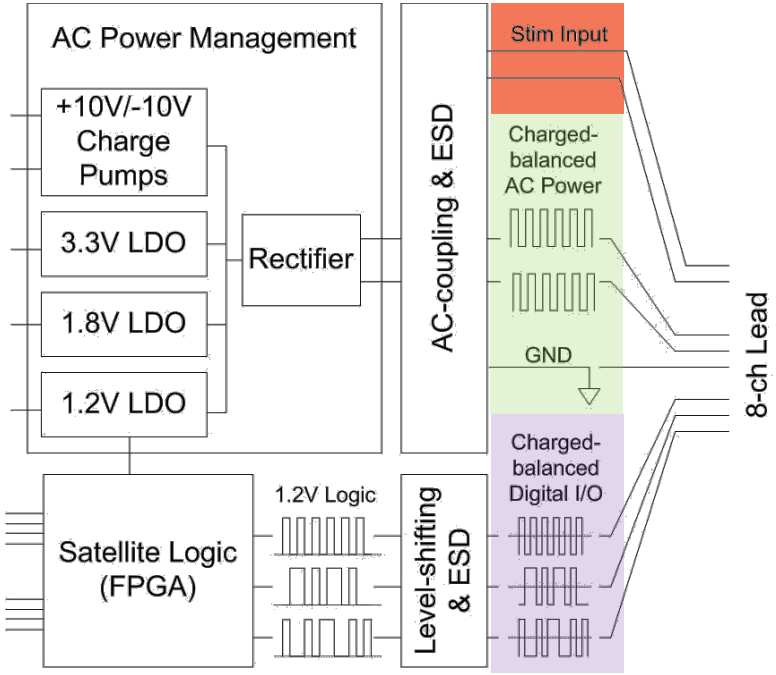
Phase 1 Satellite System: Charge Balance Interface

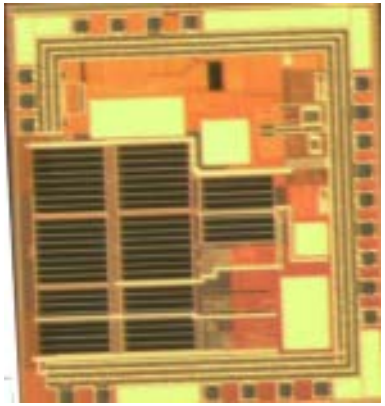
Custom AC Power Management ASIC

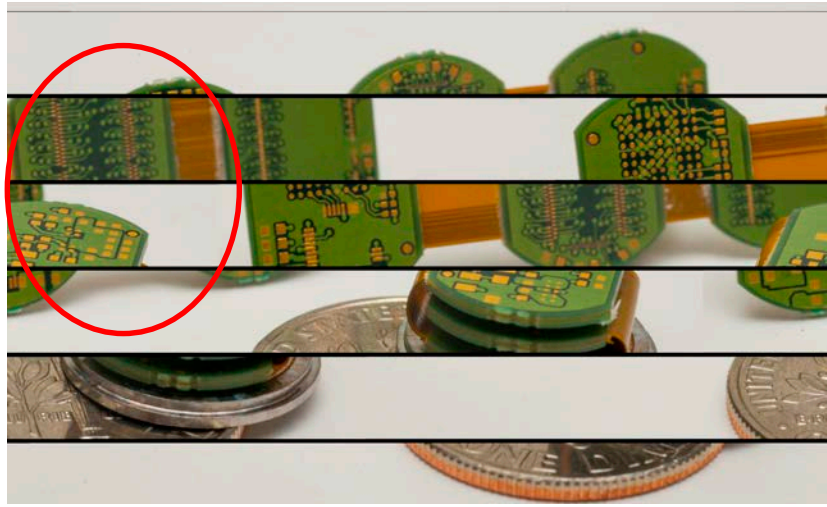
- +/- 3.7Vpp AC Inputs
- 70% Efficiency

Balanced Digital Communication

- 8b/10b Code (equal 0s and 1s)
- AC-coupled & level shift (+/-0.6V and 1.2V)
- FPGA: Coding, compression, safety







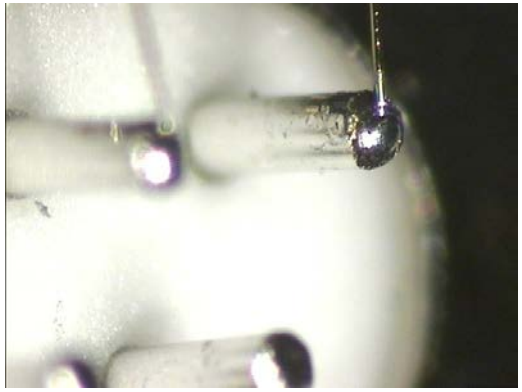
1mil Pt Wires to Pt/Ir Pins Attachment

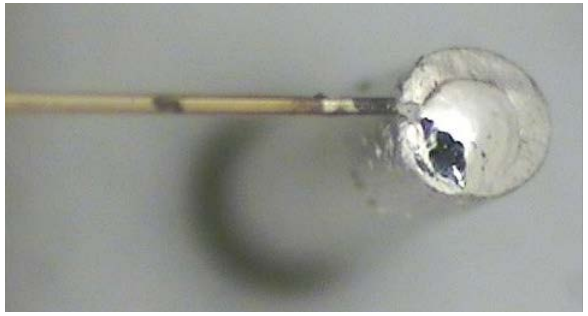
Process development tasks representative of attaching ECOG, DBS leads to the Satellite.

- Materials:
  - *Wires: 1mil Pt with insulation*
  - *Feedthroughs 8-pin (15 mil diameter 90/10 Pt/Ir)*
- Tool used:
  - *Laser welder; spot size (5mil);*
  - *Mini-vice for holding wire in place*
- Insulation material was not removed prior to laser welding

Results:

- Pt wires adhere to the pins. Discoloration observed.
- Removal of insulation at contact point would ensure more robust connection
- Template/tooling fixture would aid in ensuring full contact between the wire, feedthrough pin and laser probe is made.





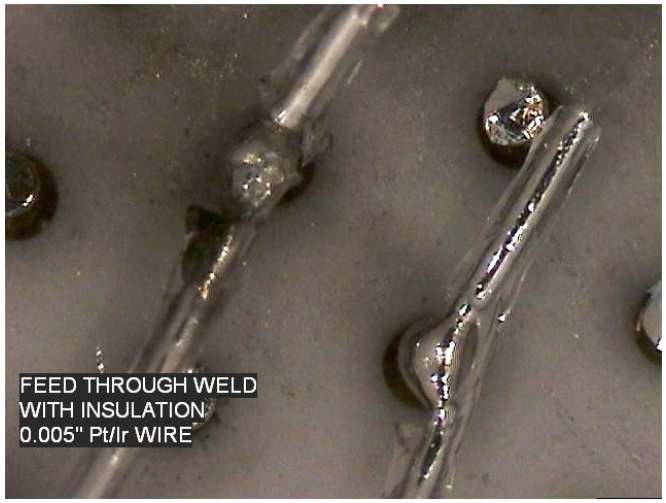
5mil Pt/Ir Wire to Pt/Ir Pins Attachment

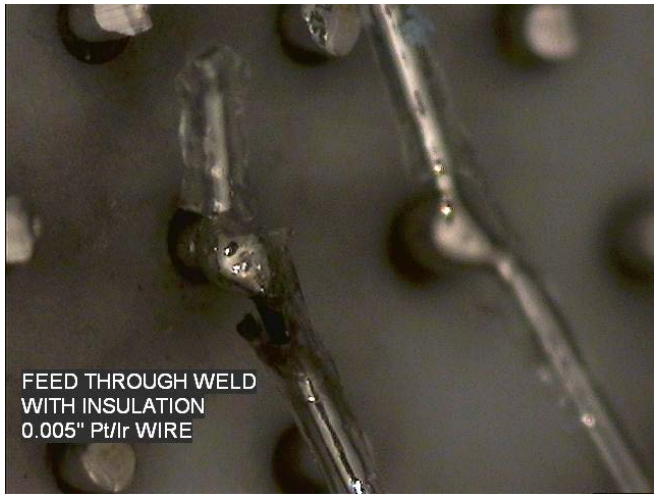
Representative Hub cable attachment to Satellite

- Materials:
  - *Wire composition: (5mil 90/10 Pt/Ir core with 1.5mil PFA insulation: total thickness = 8mil)*
  - *Feedthroughs: 81-pin (10 mil diameter 90/10 Pt/Ir)*
- Tool used:
  - *Laser welder*
  - *Mini-vice for holding wire in place*
- Insulation was NOT removed wires prior to welding.

Results:

- Pt wires adhere to pins, however, Discoloration was observed (contamination from insulation)
- Removal of insulation at contact point would ensure more robust connection





5mil Pt/Ir Wire to Pt/Ir Pins Attachment

- Insulation was mechanically stripped from the Pt/Ir wire prior to welding all samples.
- Pt wires adhere to the pins with NO discoloration
- Template/tooling fixture would aid in ensuring full contact between the wire, feedthrough pin and laser probe is made.
- Peg bonding attachment technique also evaluated for 1mil diameter wire attachment
  - *Would enable wire attachment to feedthrough pins WITHOUT the need for stripping the insulation*
  - *Successful for 1mil Au wire*
  - *Successful for 1mil Pt/Ir wire, however weld joint not as robust as Au wire (visual inspection). Possibly due to difference between Au and Pt/Ir hardness*

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Central Hub System

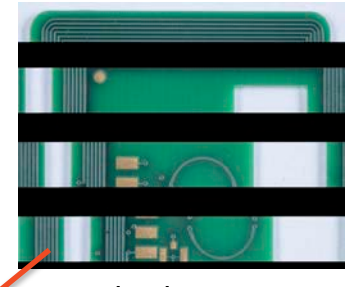
- Electronics system– PCBs, antenna with ferrite
  - *64-pin ceramic feedthrough plate with titanium flange*
  - *Alumina cover (RF transparent) with a titanium flange (hermetic seal)*

Low-Power Processor & Stimulator ASICs:

- *Neural signal processing and stimulation control*

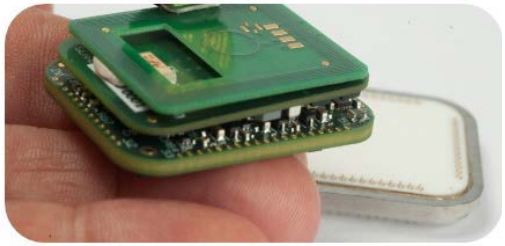
AC Power Management:

- *Power conversion and distribution to satellites*



Dual Telemetry:

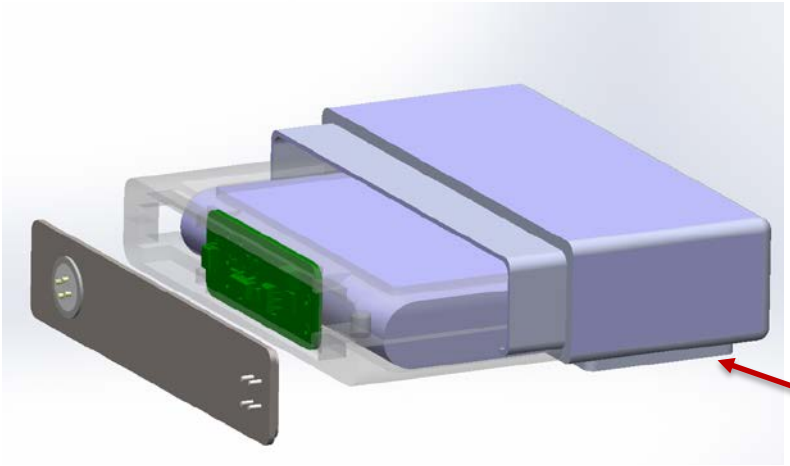
- *Long-range controller link for reprogramming & high-bandwidth link for neural data exfil to an external base station*



DRAPER

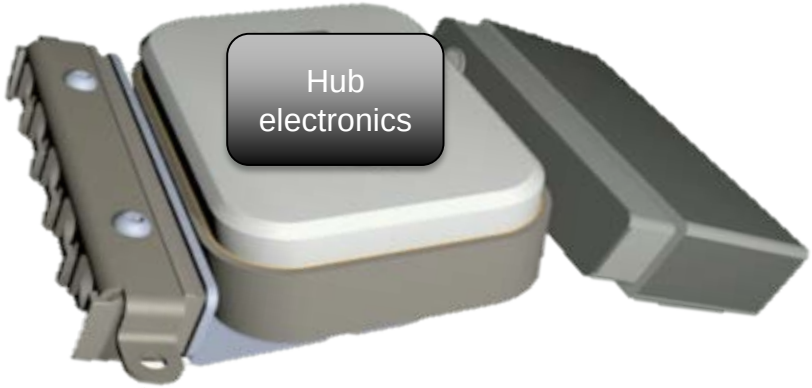
Central Hub System

- Electronics system– PCBs, antenna with ferrite
  - *64-pin ceramic feedthrough plate with titanium flange*
  - *Alumina cover (RF transparent) with a titanium flange (hermetic seal)*
- Rechargeable battery - Housing also serves as system's ground

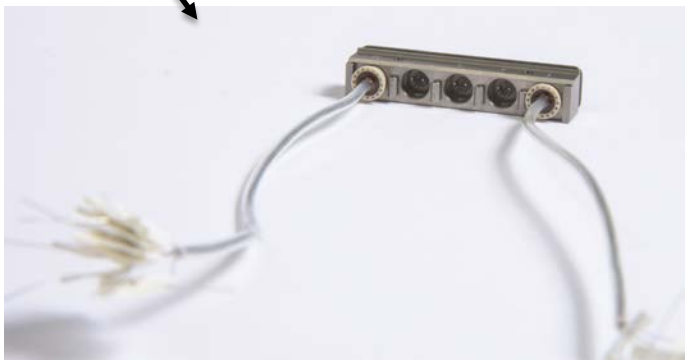


Central Hub System

- Electronics system– PCBs, antenna with ferrite
- Rechargeable battery - Housing also serves as system's ground
- High density custom connector system
  - *Housing contains 5 x 10 contacts sockets (50 contacts total)*
  - *Locking clip secures each plug/cable to housing*
  - *Each cable is hardwired to a satellite*

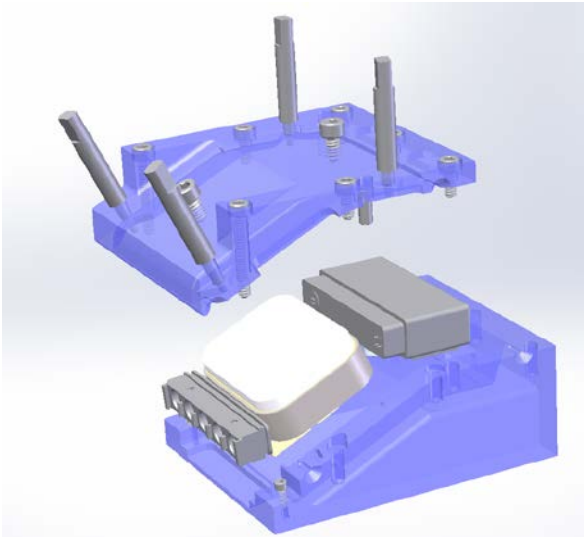


High density custom connector system



Central Hub System

- Electronics system– PCBs, antenna with ferrite
- Rechargeable battery - Housing also serves as system's ground
- High density custom connector system – Housing contains 5 x 10 contacts sockets (50 contacts total)
- Flex cable integrate electronics to connector pins
- System's curvature can be set by encapsulation tool



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Central Hub System - Modular

- Electronics system – PCB, antenna with ferrite
  - *64-pin ceramic feedthrough*
  - *Alumina cover (RF transparent)*
  - *Ti flange on both for hermetic sealing*
- Rechargeable battery – housing serves as system's ground
- High density custom connect system – housing contains 5 x 10 contacts sockets (50 contacts total)
- Flex cable integrate electronics to connector pin
- System's curvature can be set by encapsulation tool

Electronics system

64-pin feedthrough substrate

Rechargeable battery

High density custom connector system

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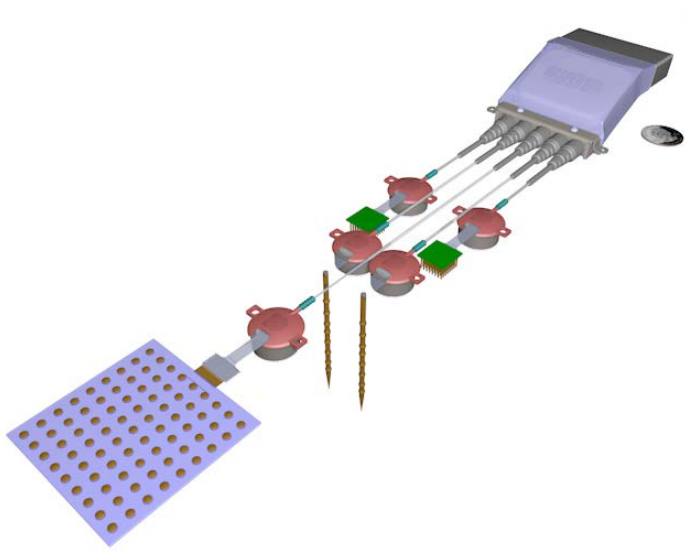
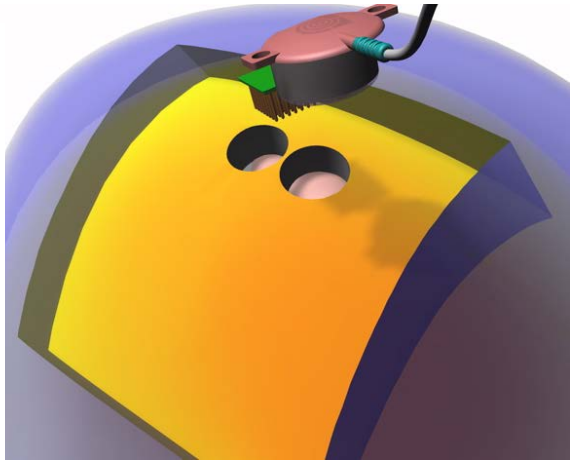
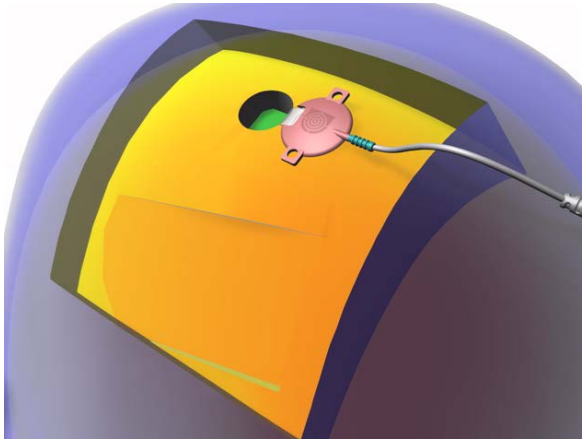
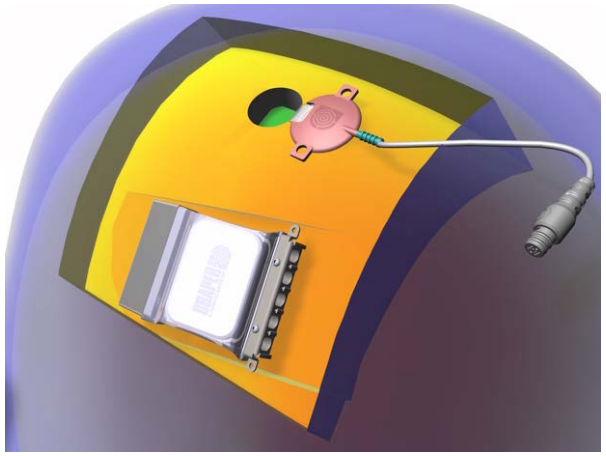
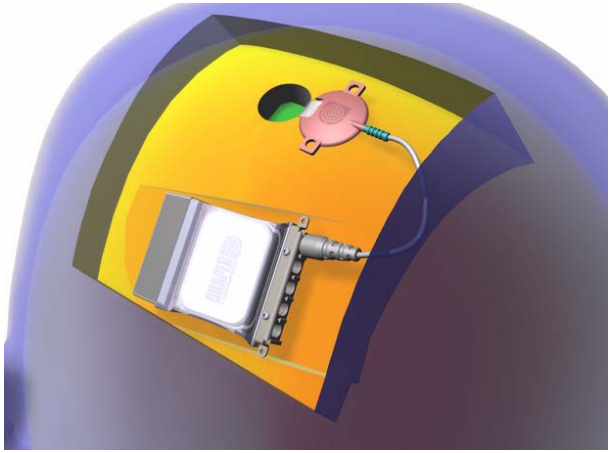
System Integration

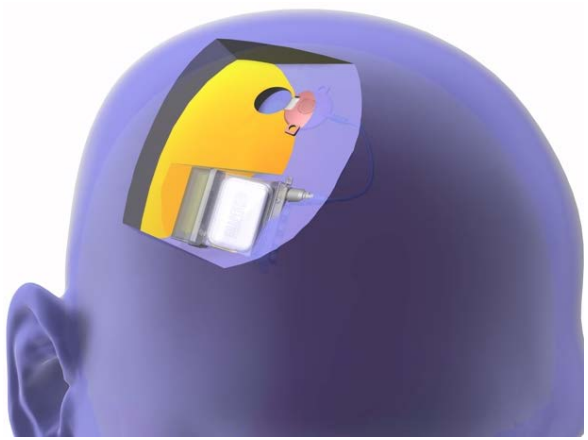












TRANSFORM DBS SYSTEM

RAPID DEVELOPMENT: FROM CONCEPT TO PROTOTYPES TO PHASE 1 HARDWARE IN < 18 MONTHS

SATELLITE ASSEMBLY

CPU PCB

POWER PCB

ANTENNA PCB

HUB PCB STACKUP

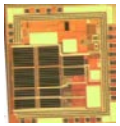
BATTERY

HUB ASSEMBLY

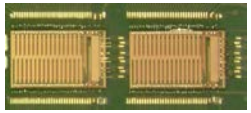
WIRELESS RECHARGE ASSEMBLY

WIRELESS RE-CHARGE (Front)

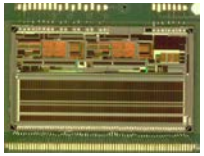
HIGH BW TELEMETRY (Back)



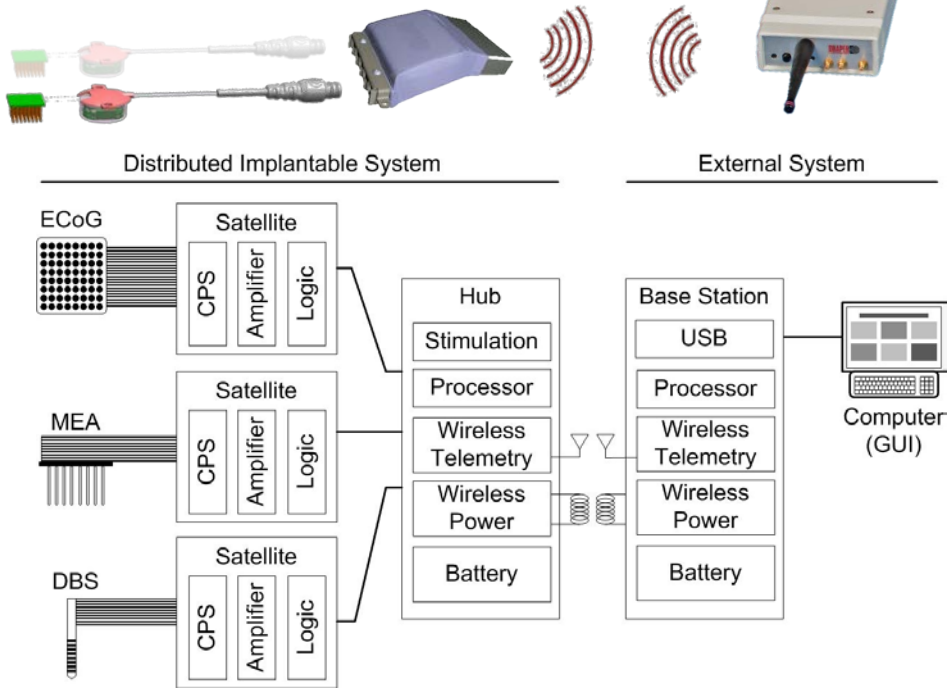
POWER MANAGEMENT



CROSS-POINT SWITCH



AMPLIFIER



LOW BW TELEMETRY

BASE STATION ASSEMBLY

BASE BOOST PROCESSING UNIT

DRAPER

Accomplishments and Future Goals

- Completed designs and prototypes
  - *Receipt of Phase 1 component pieces and tooling*
  - *Conducting process development for system packaging and integration*
- Designed a custom miniature high-density connector
  - *5x volume reduction – allows for cranial implant of high channel count system*
- Increased capability of existing commercial electrodes
  - *Improved channel count by 4x*
  - *Faster path to human use*
- Mature technologies
  - *Patent applications filed*

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