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

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Abstract - An implanted neural stimulator with closed loop control requires electrodes for stimulation pulses and recording neuron activity. Our system features arrays of 64 electrodes. Each electrode can be addressed through a cross bar switch, to enable it to be used for stimulation or recording. This electrode switch, , a bank of low noise amplifiers with an integrated analog to digital converter, power conditioning electronics, and a communications and control gate array are co-located with the electrode array in a 14 millimeter diameter satellite package that is designed to be flush mounted in a skull burr hole. Our system features five satellite packages connected to a central hub processor-controller via ten conductor cables that terminate in a custom designed, miniaturized connector. The connector incorporates features of high reliability, military grade devices and utilizes three distinct seals to isolate the contacts from fluid permeation. The hub system is comprised of a connector header, hermetic electronics package, and rechargeable battery pack, which are mounted on and electrically interconnected by a flexible circuit board. The assembly is over molded with a compliant silicone rubber. The electronics package contains two antennas, a large coil, used for recharging the battery and a high bandwidth antenna that is used to download data and update software. The package is assembled from two machined alumina pieces, a flat base with brazed in, electrical feed through pins and a rectangular cover with rounded corners. Titanium seal rings are brazed onto these two pieces so that they can be sealed by laser welding. A third system antenna is incorporated in the flexible circuit board. It is used to communicate with an externally worn control package, which monitors the health of the system and allows both the user and clinician to control or modify various system function parameters.

Keywords - Neural stimulation - Deep brain; Neural interfaces - Implantable systems; Neural interfaces - Microsystems and microfabrication

I. Introduction

A. System Requirements

The packaging scheme illustrated in this paper for an implantable electronics system was designed to address the need to create a multi-node, closed-loop, wireless neural system in response to the DARPA BAA-14-09 for Systems-Based Neurotechnology for Emerging Therapies (SUBNETS). There are a number of parameters related to packaging which the system must address during the two phases of this program, for example, the number of target sites, number of electrodes/channels per site, implant duration, size and weight of the implant, as highlighted in Table 1, as well as more general requirements associated with implanted devices [1].

Along with the requirements detailed in the Broad Agency Announcement (BAA), there are several FDA requirements specific to the packaging of an implantable system that must be met. These include hermeticity, impact, operating temperature, and biocompatibility [2],[3].

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TABLE 1: REQUIREMENTS DERIVED FROM THE DARPA BAA-14-09

Parameter	Phase One	Phase Two
Number of sites	Four recording, one stimulating	Four recording, four stimulating
Electrodes per site	25 recording, 25 stimulating	50 recording, 50 stimulating
Duration of implant	90 days	> 2 years
Time between recharge/battery replacement	30 days	Inductive recharging
Size of implant	40mm x 40mm	30mm x 30mm
Weight of implant	35 g	25 g

B. *Package System Architecture*

Our implantable system is based upon an architecture that consists of a central hub connecting to multiple satellite devices, Fig. 1. Each satellite is connected to a high density electrode, and a cable which connects to the central hub, both of which are hardwired connections. The cable from the satellite plugs into a connector header intergrated within the main hub system. The connector header is designed to allow up to 5 discrete satellite systems to be connected to the central hub. The use of the plug-in style connection between the individual satellites and the hub provides the ability to use one main hub system with a selection of satellite-electrode systems, providing the opportunity to configure and optimize each implant for specific cases and based on the clinical requirements and sites for recording and stimulation.

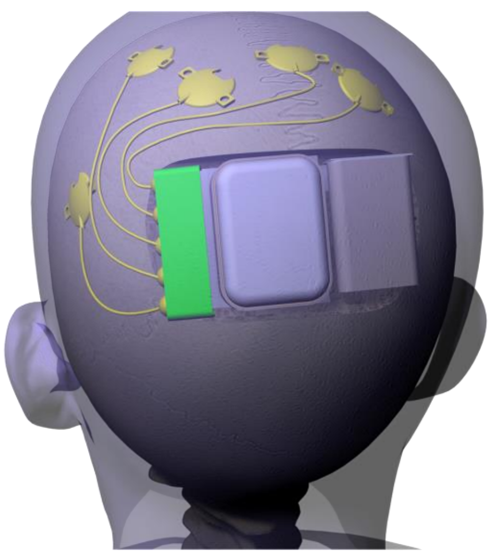


FIGURE 1: ILLUSTRATION OF THE PACKAGING ARCHITECTURE OF INDIVIDUAL SATELLITES CONNECTED TO A MAIN HUB SYSTEM.

SATELLITE SYSTEM

C. *Overview*

The satellite includes front end electronics for the probe array, power conversion, and communications with the hub controller. This is a significantly more complex electronics package than used in other implanted stimulating and recording systems [4],[5]. The package for the satellite was design with the goal to fit within a 14mm diameter bur hole created by the surgeon. The bulk of the package would sit within this hole, and a top cap would hold the connections to the system hub and electrodes in place. The cap would also include capture holes to allow the surgeon to anchor the cap to the skull and provide a smooth surface interface to the skin. An overview of the satellite package design connected to a microelectrode array and the cable for connecting to the hub system is shown in Fig.2.

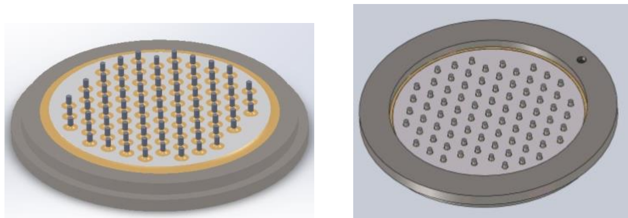
FIGURE 2: ILLUSTRATION OF THE SATELLITE SYSTEM CONNECTED TO A MICROELECTRODE ARRAY AND A HUB SYSTEM CABLE.

D. *Satellite Device Enclosure*

Details of the physical design are outlined in Table 2. The satellite package enclosure is comprised of a ceramic feedthrough plate fabricated from 95% alumina and a titanium can. An array of 0.25mm diameter platinum-iridium pins (90%Pt/10%Ir) are brazed into the ceramic disk using pure gold. These pins provide the electrical connection between the interior circuitry and the electrode and hub cable attached on the exterior side of the plate, Fig. 3.

TABLE 2: PHYSICAL DESIGN SPECIFICATION OF THE SATELLITE ENCLOSURE.

Feature	Value	Comments
Size	13.74 mm diameter, 8mm tall	Fits within a 14mm diameter surgical burr hole (neurosurgeon input)
I/O	81 pins on 0.970mm pitch	64 for electrode; 10 for hub
Package (enclosure) materials	Alumina base feedthrough plate; Titanium cover	To meet hermetic; biocompatibility specification
Package seal	Titanium seal ring on feedthrough plate for laser welding	To meet hermetic specification
Wire attachment	Thermo-sonic bond	Assembly vendor will determine best practice
I/O encapsulation	Epoxy filled plastic shell	Provides strain relief for the wires



(Internal Side) (External Side)

FIGURE 3: ILLUSTRATION OF THE INTERNAL AND EXTERNAL SIDE OF THE SATELLITE CERAMIC FEEDTHROUGH PLATE.

The hermetic seal of the package is achieved by laser welding the can to the titanium flange that is brazed onto the ceramic feedthrough plate.

E. Rigid-Flex Physical Design and Assembly

The satellite electronics board is a rigid-flex design comprised on three rigid boards with flex connection. This design allows for the board to be folded upon itself to fit within the internal dimensions of the satellite enclosure of a 12.8mm diameter and approximately 7mm height. Titanium cans of different heights can be machined to accommodate taller rigid-flex designs, for example if a double sided board were required.

The circuit board contains four bare dies, a chip-scale package, and several passive components. Due to the fine pitch of the contacts on several of the bare dies, sub 25µm diameter wire bond attachment is required. The bare dies would be attached first. A glob top layer would then be applied to protect the bare dies and wire bonds during the surface mount attachment and reflow process of the remaining components. The assembly process of the rigid-flex board would be conducted in the flat configuration.

The rigid-flex board is attached to the pins of the feedthrough plate by solder attachment. Nonconductive epoxy is then applied and wicked into the area between the board and feedthrough plate for additional reinforcement of the bond. Once the board is attached to the feedthrough plate, the first flex bend is formed and secure using conductive epoxy. The second bend is then formed. Once the rigid-flex board is attached and folded, the satellite package is hermetically sealed by laser welding. Full and cross sectional views of the satellite enclosure containing the rigid-flex circuit board is shown in Fig. 4.

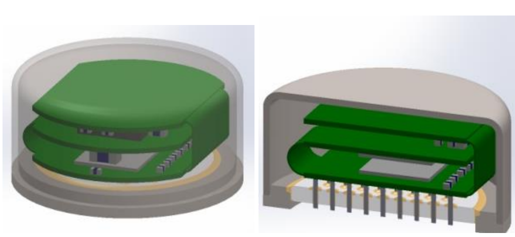


FIGURE 4: FULL AND CROSS SECTION ILLUSTRATIONS OF THE SATELLITE SYSTEM.

F. Cable Attachment and Encapsulation

A cable for connecting the hub and up to four different styles of electrodes/leads would be hardwired to the external side of the satellite feedthrough plate. Laser welding or resistance welding would be used for the cable attachment process. The external side of the feedthrough plate contains a recess for the wire to be positioned into and attach to the pins, Fig. 5. The recess allows provides strain relief of the wires after they are encapsulated. The wire cap is then attached to the satellite using epoxy and over-molding in silicone. The anchor points on the cap are used for securing the satellite to skull after it is recessed into the bur hole.

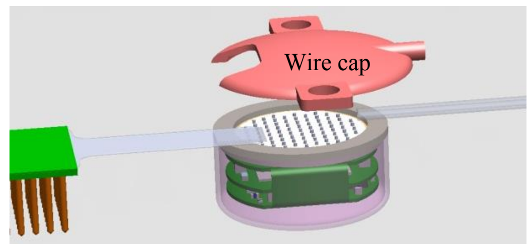


FIGURE 5: SATELLITE SYSTEM ILLUSTRATING THE FEEDTHROUGH PLATE RECESS FOR WIRE ATTACHEMENT AND THE WIRE CAP USED FOR PROTECTION OF THE WIRES AND SECURING THE SYSTEM TO THE SKULL.

II. HUB SYSTEM

A. Overview

The System Hub consists of four main components: (1) ceramic package which houses the electronics, (2) a connector for integrating the System Hub to the Satellites, (3) a rechargeable battery, and (4) a flex cable which integrates the first three components. Table 3 outlines the features of the design, and an illustration is shown in Fig. 6.

TABLE 3: HUB SYSTEM PHYSICAL SPECIFICATION.

Feature	Value	Comments
I/O	64 on 1.27mm (0.050 in) pitch	Dependent on contacts between hub and individual satellite plus battery contacts
Package Materials	Alumina plate and cover with titanium seal ring; liquid crystal polymer (LCP)/polyimide flex cable, Titanium enclosed battery	To meet hermeticity, impact, biocompatibility specifications; ceramic cover for RF transparency
Flex to package attachment	AuSn solder or wire bond	Based on discussions with assembly houses on preferred methods

I/O encapsulation	Epoxy	N/A
Package seal	Titanium band for laser welding	To meet hermeticity specifications
Package encapsulation	Silicone rubber	To meet hermeticity and impact specifications; strain relief/device comfort
Battery encapsulation	Titanium can	Biocompatibility and impact specifications

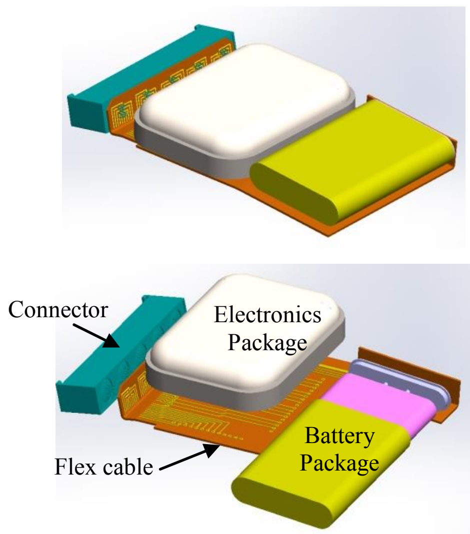


FIGURE 6: ILLUSTRATION OF THE HUB SYSTEM OVERVIEW (TOP) AND EXPLODED VIEW (BOTTOM).

B. *Hub System Electronics Enclosure*

Similar to the design of the feedthroughs for the satellites, the feedthroughs for the hub system consist of a 95% alumina substrate with a brazed titanium flange. A perimeter array of 64 platinum/iridium pins, 90/10% respectively, are gold brazed into the ceramic. The exterior footprint of the package, as shown earlier in Fig. 6, is 30mm x 40mm with the overall height determined by the cover height. The cover is also fabricated from alumina, which provides the RF transparency required for wireless communication to the antennas located on the top circuit board within the enclosure [6]. A titanium flange, similar to that on the feedthrough plate, is brazed to the cover and provides the hermetic seal for the package. The height of the cover is dictated by the number of circuit boards and its heights based on the components. The cover design uses the titanium flange as the bulk of the height is the side walls. With the ability to trim the titanium as needed, the design provides the flexibility for accommodating the maximum internal height needed as well as the potential for reducing the overall package height with a reduction of the electronics.

In this design, the bottom printed circuit board containing the majority of the electrical components will attach to the feedthrough substrate. This board will contain holes allowing it to drop into the pins of the feedthrough plate. A second component, if needed, will then attach to the bottom board via a board-to-board connector or pins. The top board contains the antennas with a ferrite material attached to its bottom side, Fig. 7.

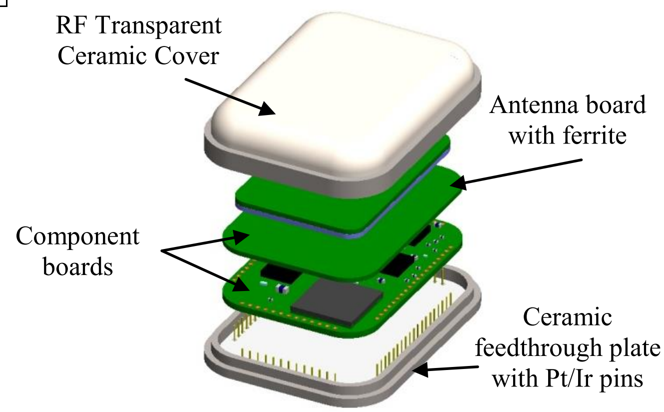


FIGURE 7: EXPLODED VIEW OF THE HUB SYSTEM ELECTRONICS PACKAGE.

C. *Rechargeable Battery Enclosure*

The selection of the rechargeable battery for this system was based on both its physical and electrical properties. Due to the size and weight limitation for an implantable system, the goal was to incorporate a battery no larger than $710mm^2$ and 6mm thick, with a weight less than 10g. After research into commercially available rechargeable batteries appropriate for implantable applications, the Quallion QL0200I-A cell was chosen. To integrate this cell into the hub system, it will be enclosed in a titanium sleeve and attached to the flex cable using a header, shown previously in Fig. 6. The use of the secondary housing allows for additional electronics to be placed with the battery, as well as providing additional protection for hermeticity and meeting the impact specification of 2.5 Joules.

D. *Plug and Socket Connector*

The connection between the individual satellites and the main hub systems must withstand up to 6 connect/disconnect cycles. To achieve this, the satellites will be connected to the hub using plugs that are inserted into a single socket which is bonded to the hub flex circuit. Due the high number of contacts between the hub system and satellites, 10 contacts per satellite, commercial connection systems designed for medical implant applications exceeded the targeted footprint of 10mm x 40mm. Based on commercial circular connector system, a modified and custom design concept was developed for a nano-circular connector system.

The housing consists of a titanium shell and five discrete sockets, one per satellite. A biocompatible insulator material encapsulates each individual pin within the socket, and guiding pins to ensure the plug is inserted in the correct orientation. The mating plug has a silicone overmold which seals the connector housing to the cable, provides strain relief, and increases the strength and durability of the connector. The design incorporates dual O-rings for additional protection against fluid ingress and increase seal integrity, which could be incorporated into the socket or plug, Fig 8.

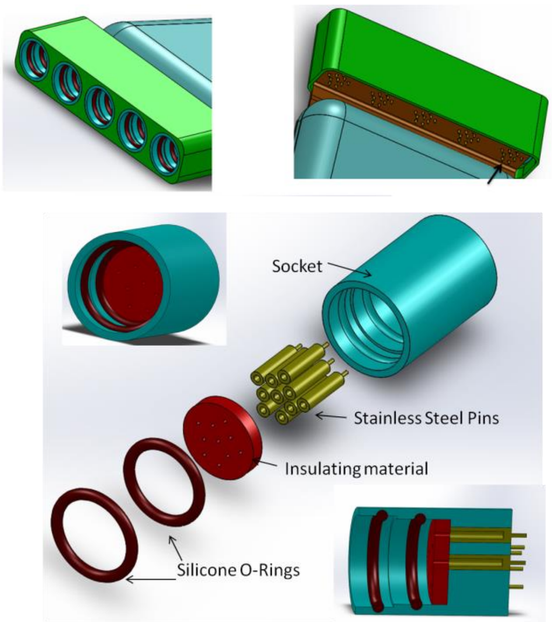


FIGURE 8: ILLUSTRATION OF THE CONNECTOR HOUSING AND SOCKET FOR LINKING THE INDIVIDUAL SATELLTIES UP TO THE CENTRAL HUB SYSTEM.

E. Flex Interconnect Cable

The hub system modular components of the electronics package, rechargeable battery, and connector system are integrated together using a flex cable fabricated from liquid crystal polymer (LCP) or polyimide, Fig. 9.

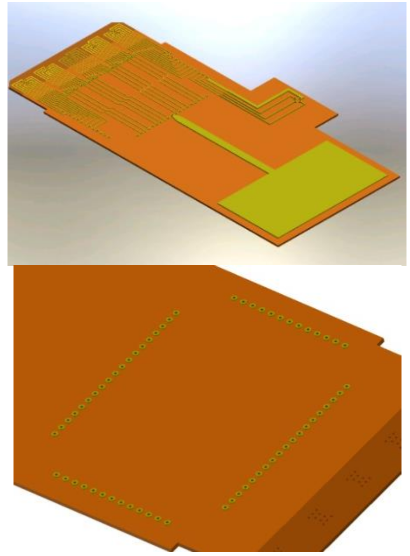


FIGURE 9: ILLUSTRATION THE TOP AND BOTTOM SIDE OF THE FLEX CABLE.

The cable is constructed of one interconnect layer with a top and bottom ground plane. There are two potential options that for attaching the flex cable to the ceramic package; wire bonding of the package's feedthroughs to the pads on the cable, and a reflow process where gold-tin solder bumps on the hub are reflow attached to the contacts on the flex cable. As with the other components of the implantable system, the flex cable needs to meet biocompatibility specification as well as the electrical isolation and conductivity requirements of the system. After all the components of the hub systems are integrated together, the hub system is then over molded with silicone to provide additional protection to the system and a smooth, contoured shape.

III. SUMMARY

An implantable neurological recording and stimulation system with closed loop control has been designed, which utilizes architecture of distributed electronic packages. Engineering of all major components of the system has been completed and all meet design and regulatory requirements. Fabrication and assembly of system components has commenced.

ACKNOWLEDGMENTS

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