KDI: A wireless power-efficient modular platform for pre-clinical evaluation of implantable neural recording designs

M. Foerster, F. Burdin, F.Seignon, A. Lambert, C. Vasquez and G. Charvet

Abstract—**This paper presents a power-efficient modular wireless platform which has been designed for prototyping and pre-clinical evaluations of neural recording implants. This Kit for Designing Implants (KDI) is separated in function specific modules of 34x34mm which can be assembled as needed. Five modules have been designed and optimized for ultra-low power consumption and a protective casing has been designed for pre-clinical trials. Two different wireless modules have been compared and the KDI performances have been evaluated in terms of modularity, wireless throughput and power consumption.**

I. Introduction

Intracranial neural recordings have been used in many applications in order to better understand how the brain works, how it dysfunctions and how disorders may be cured. Several techniques are employed for recording the electrical activity of the brain. Local field potentials (LFP) can be recorded in relevant areas of the brain by using relatively large electrodes of several square millimeters, which can be placed in the depth of the brain for StereoElectroEncephalography (SEEG) recordings or on the surface of the cerebral cortex for ElectroCorticoGraphy (ECoG) recordings. The LFP recorded by this technique have amplitudes of several tens of microvolts and frequencies of interest lie in the 1Hz – 300Hz range. Microelectrodes can be used to record the activity of much smaller populations of neurons and down to single units. The features of interest of these recordings are the "spikes" emitted by single neurons. These spikes last approximately 1ms, have amplitudes of several ten to hundred microvolts and are typically recorded at sampling rates of 10 to 50 kSps [1][2].

While neural recordings used to be performed by external devices tethered to the electrodes, miniaturization and advances in wireless communication have driven towards the development of implantable devices [3][4][5][6]. In particular, CLINATEC has developed a wireless 64-channel ECoG recording implant for long term clinical applications [7]. These implants incorporate the amplification and digitization of the neural signals as well as means of communication and often other features like sensors, means of measuring the electrode impedance or electrical stimulation. For clinical studies, these fully implantable devices reduce the risk associated with transcutaneous connectors but carry severe regulatory constraints regarding, among others, biocompatibility, tissue heating, non-ionizing radiation emission and leakage currents. For pre-clinical studies, the applicable regulations are milder, transcutaneous connectors are often used and behavioral studies and study of cognitive tasks take advantage of greater freedom of movement using wireless devices [8].

Depending on the application, a neural recording implant may be required to record LFP or spikes, from single or multiple locations of the brain, perform real time analysis of the recorded signals, stream the signals to a PC or electrically stimulate the electrodes. Nevertheless the underlying architecture is more common than it seems: in any case the implant needs a way to communicate with an external device and interpret user commands, it requires the means of powering its different components and needs to comply with applicable regulations.

Our approach is therefore the following: we have designed a platform for evaluating and designing solutions for performing intracranial neural recordings which is adaptable to different needs. This Kit for Designing Implants (KDI) will be modular and generic enough for being extended with several application-specific solutions, while being integrated enough for allowing pre-clinical trials on large animals (non-human primates and mini-pigs). It will contain the common architecture required for a neural recording implant and be separated in function-specific modules corresponding to the needs of the application (e.g. ECoG or spike recording, data analysis or wireless streaming). Moreover, it will integrate from start the constraints associated with class III active implantable medical devices in order to reduce the time needed from pre-clinical proof of concept to clinical trial. One of the first applications of the KDI will be the development of future generations of WIMAGINE (see [7]) implants.

II. System objectives and architecture

A. System objectives

The purpose of the KDI is to be able to evaluate specific functional building blocks or design approaches before incorporating them into a fully implantable device. The best way to evaluate these building blocks is during pre-clinical trials. The size of the platform is therefore a compromise between the need of easily developing and evaluating new modules, and the need of being able to evaluate its functions during untethered animal experiments. Dimensions of 34mm x 34mm were therefore chosen for the printed circuit boards (PCBs) with an inter-board spacing of 5mm. A custom designed housing will protect the electronics during experiments and will allow for easy change of battery or external storage card.

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B. Architecture

In order to build an upgradable platform where specific functions can be easily added or enhanced, without needing the replacement of the whole design, the KDI was made up of separate printed circuit boards (PCBs), sharing a common connector, and containing each a particular function. Five different modules have been built so far and can be assembled for different applications: the “Main module”, “Power module”, “ECoG recording module” and two “Communication modules”, which will be detailed in the next sections.

1) KDI-Main module

The KDI-Main module is a 6 layer 34mm x 34mm PCB comprising a microcontroller (MSP430F5638, Texas Instruments) which controls the other modules and handles the interface with an external control unit. Several sensors have been implemented in this module: accelerometer (ADXL362, Analog Devices), humidity sensor (SHT21S, Sensirion), temperature sensor (TMP20, Texas Instruments), current sensors (MAX9938, Maxim Integrated) and power supply voltage sensor, which can all be deactivated in order to reduce power consumption if not needed in the final application. Two external non-volatile memories have been implemented: a 2Mbit SPI FRAM memory (FM25V20, Cypress Semiconductor) for short term storage or firmware backup and a slot for a removable microSD card. Level shifters were used between the MSP430 and its peripherals in order to run each with its lowest operating voltage which is supplied by DC/DC (LTC3388, Linear Technology) converters in order to maximize efficiency. A USB connector allows direct communication between a PC and the MSP430 and a pushbutton and several LEDs are also provided.

The firmware running on the MSP430 has been designed in agreement with the hardware architecture: it is organized in different layers and modules in order to very easily remove firmware of a particular module if not needed in the final application. This approach keeps the firmware as concise as possible and will make future IEC62304 certification much easier. Moreover, the firmware has been optimized for ultra-low power by taking advantage of the many peripherals of the MSP430 and in particular its low power modes.

2) KDI-Power module

The purpose of the Power module is to supply power to all other modules and handle the charge of a rechargeable Lithium-ion battery. The battery can be recharged through an inductive field at 13.56MHz or through USB. An input for energy harvesting sources such as piezo or thermal elements is also available. The power source provided to the other modules is chosen automatically between battery and external source and can be hot-swapped. USB data and power isolation have been implemented according to IEC 60601-1 in order to ensure safety when using the platform directly connected to a PC. Furthermore, a simple ISO14443B RFID communication module (RF430CL330, Texas Instruments) has been implemented as a backup communication link between an external unit and the platform. This RFID link could be used as a low throughput primary communication channel, as a secondary channel dedicated to reprogramming the MSP430 wirelessly, or for implementing the synchronization method described in [9].

3) Communication module

The bottleneck of wireless recording systems is often the wireless data link. Indeed, ECoG recordings generate typically 12kbps per channel (1kSps @12bit) and spike recording require at least 120kbps per channel (10kSps @12bit). For applications requiring the streaming of the neural recordings to an external unit, a low-power, high-throughput wireless link is needed. For applications requiring embedded analysis of the recorded signals, only acquisition parameters such as selected channels or gain and the result of the processing will be exchanged between the implant and an external unit and therefore do not require a high throughput link but will rather save the power for the processing unit.

In order to optimize the link for both high and low throughput applications, two separate modules built around two different commercial transceivers (TABLE I.) were developed. The firmware handling communication between the implant and an external unit has been separated in layers with clearly defined interfaces, in order to keep the physical implementation of the communication link transparent to the application. Thanks to this approach, a new communication module can be implemented very easily into the complete application.

a) KDI-nRF module

The center component of this module is the nRF24L01+ from Nordic Semiconductor. The nRF24L01+ operates in the 2.45GHz range with a GFSK modulation, over-the-air data rate of up to 2Mbps, an output power of maximum 0dBm and is interfaced with the main module through SPI and 2 GPIO. Its Media Access Control (MAC) integrates the Nordic “Enhanced ShockBurst” for packet assembly and error detection. The nRF24L01+ was used in combination with a PCB antenna and a LDO regulator.

b) KDI-ZL module

The center component of this module is the ZL70321 from MicroSemi. It operates in the Medical Implant Communication Service Band (MICS) at 402–405MHz, has an over-the-air data rate of up to 800kbps, a maximum output power of -1dBm and is interfaced through SPI and 2 GPIO. Its MAC handles forward error correction and CRC error detection and achieves a maximum Bit Error Rate (BER) of $1.5x10^{-10}$. The ZL70321 was integrated on a 34mm x 34mm PCB along with two antennas: a 2.45GHz antenna for the ultra-low power wake-up and a 400MHz chip antenna for communication in the MICS band (Fig. 1). An SMA connector is also provided for improving performances using an external antenna.

TABLE I. COMPARISON OF NRF24L01+, ZL70321

	Nordic nRF24L01+	MicroSemi ZL70321
Carrier freq.	2450 MHz	400 MHz
Raw data rate	2 Mbps	800 kbps
Interface	SPI	SPI
TX current	11.3 mA	5.1 mA
RX current	13.5 mA	5.1 mA
Sleep current	900 nA	250 nA
Range	> 10m	2m

4) KDI-CINESIC32 ECoG recording module

A neural interface module has been designed for amplifying and recording ECoG signals. This module is built around the CINESIC32 ASIC [10] specifically designed for recording ECoG signals and which the authors have previously successfully used. This ASIC features sampling frequencies of 400Hz, 600Hz, 1kHz and 3kHz, analog gains of up to 1300 and an input referred noise of 0.7µV_{RMS} has been measured in [11]. Power is supplied to the CINESIC32 by the power module and regulated by a 3.3V LDO (LP5907, Texas Instruments). The main module is interfaced with the ECoG recording module through SPI and several GPIO, protected by level shifters (74LVC2T45, Texas instruments) in order to account for differences in supply voltages. High voltage switches (ADG1414, Analog Devices) are placed between the ASIC and the electrode connector in order to ensure compatibility with a future stimulation module (Fig. 1). A series capacitor protects the patient from any DC leakage current as requested by IEC 45502-1.

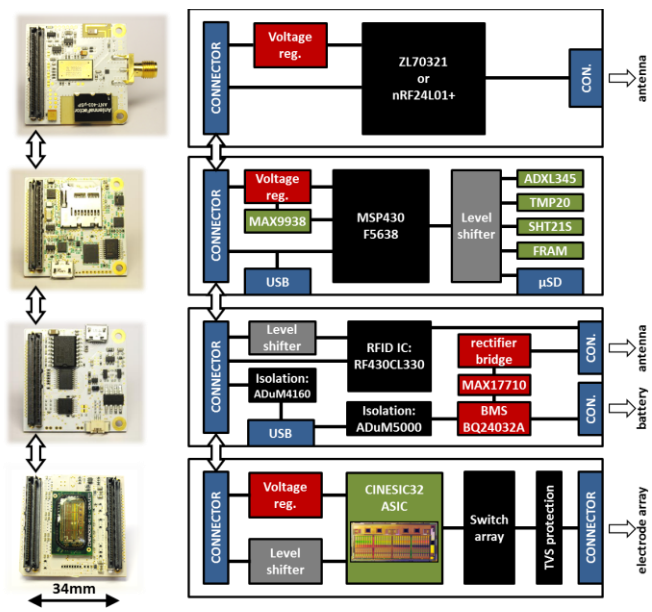

Figure 1. Architecture of the different modules and interaction of these. Represented are (from top to bottom) KDI-ZL, KDI-Main, KDI-Power and KDI-CINESIC32.

C. PC interface

A LabView interface has been designed for interfacing the platform from a PC using a custom high level communication protocol. It allows reading each sensor, performing various tests, starting an acquisition and displaying the acquired data. The interface has been designed using LabView because it is easily adaptable and expandable; for experiments requiring a tool-chain for performing real-time signal processing the KDI has been made compatible with the C++ written PC interface described in [7].

D. Mechanical housing

For performing in vivo tests on large animals (non-human primates) a plastic casing has been designed to protect the stack of electronic PCBs from the pre-clinical environment. This casing had to adapt onto the existing connector (PL900, Amphenol) available on the head of primates already implanted with epidural electrode arrays for tethered experiments and be able to contain an assembly of up to five modules of the platform (Fig. 2). Ethical approval for the pre-clinical trials has been obtained and experiments were performed in accordance with European council directives.

While the final protective casing will be made out of polyether ether ketone (PEEK), a preliminary case has been 3D-printed using polyamide. It can be adjusted on the existing transcutaneous connector and the stack of assembled modules fits well inside.

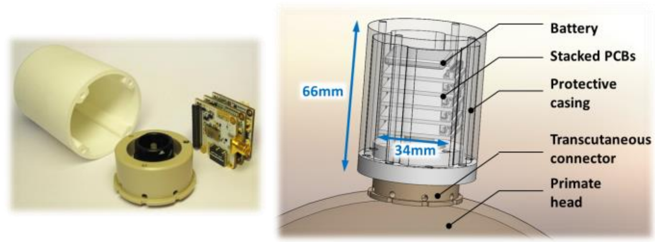

Figure 2. Right: 3D model of the protective casing and the assembled PCBs on a non-human primate head. Left: 3D-printed housing next to a KDI stack and a transcutaneous connector.

III. Preliminary Results

A preliminary performance evaluation has been performed with a focus on power consumption and RF performances. The results will be detailed in the following sections.

A. RF performances

The RF performances of the system were evaluated using the KDI-nRF and the KDI-ZL modules, the KDI-main module running the corresponding firmware and the KDI-Power module attached to a Li-ion battery. The base station was made of a main module and the appropriate RF module and attached to a PC through USB.

For evaluating the KDI-ZL module, a miniature ¼ wave monopole antenna (RF Solutions) was connected to the module on the "implant" side. On the base station side a MicroSemi ZL70120 was used together with a dipole antenna (Adactus). An effective application throughput of 440kbps could be achieved at distances of up to 2m in free space. The power consumption of the implant module was measured at 30mW at maximum throughput.

The KDI-nRF module was evaluated using one module as a primary transmitter in an implant, and one as a primary receiver in a base station. An application data throughput of 330kbps could be achieved at distances of up to 15m in free space. The power consumption of this module on implant side at maximum throughput was measured at 31mW.

The power consumptions of both RF modules have been measured as a function of the throughput and compared in Fig. 3. The Zarlink module offers a higher throughput than the nRF24L01+ module and outperforms it regarding power efficiency at high throughputs, but offers no power saving at low application throughputs. The nRF module presents better performances for applications requiring a long range or a low throughput while the Zarlink module will be preferred for applications requiring high throughputs at short range.

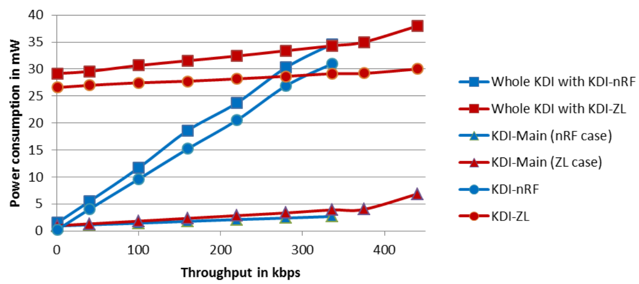

Figure 3. Detailed power consumptions of the assembled KDI modules, when using the KDI-nRF or the KDI-ZL as a function of the wireless application throughput.

B. *Power consumption*

The power consumption of the platform was measured by connecting a 320mAh Li-ion rechargeable battery (LP402933, Bak) to the power module. The consumptions of the different modules were measured during the 3 main states of the platform: "stand-by" (awaiting wireless connection), "connected" (no application data exchange) and "streaming at 300kbps". The results are displayed in Fig. 4 and confirm the results of III.A: in standby mode the assembled KDI will draw on average 220µA of a 3.7V Li-ion battery when using the KDI-nRF module, while it will draw 720µA when using the KDI-ZL module. The difference in power consumption increases when the implant is connected to the base station without exchanging any data because the consumption of the ZL70321 is not much influenced by the application throughput. At last, the power consumptions of KDI with KDI-nRF and KDI with KDI-ZL are almost equivalent at respectively 34.6mW and 34.3mW when the requested load reaches the nRF limit at 330kbps (Fig. 3).

Through these measures and those of [11] it is estimated that the consumption of the KDI platform will be 50mW during the streaming of 32 channels of ECoG data at 1kHz and 0.75mW during stand-by, using the KDI-ZL module for communication. This would allow performing continuous in vivo recordings of up to 24 hours, or recordings of 2 hours/day during 10 days using a LP402933 battery.

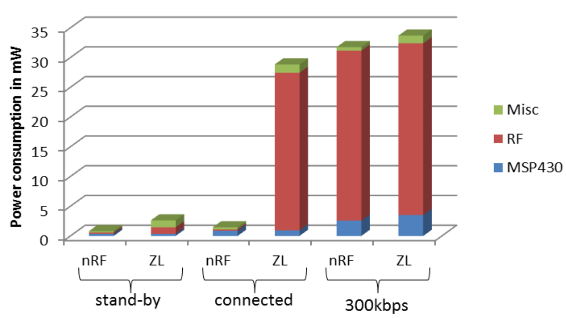

Figure 4. Comparison of power consumptions between different states for nRF-based and Zarlink-based wireless communication links. During stand-by the implant periodically listens for incomming connexion requests, average power consumptions are displayed.

IV. Conclusion & Future Work

A modular platform for evaluating building blocks for implantable applications has been designed and optimized for low power applications. Two different wireless communications modules have been designed proving the modularity of the KDI platform. Both wireless modules could be compared in terms of achieved throughput and power consumptions. The measured power consumptions are low enough for in vivo experiments without disproportionate batteries and the achieved size is acceptable for experiments on non-human primates.

Future work will include the evaluation of the ECoG recording module on non-human primates and the developments of new modules for evaluating new functionalities. These will include a module for performing single unit recordings, a module for electrical stimulation and a module for embedded processing. After validation, the schematic of a stack of modules can also be easily sized down onto a single PCB for fully implantable applications.

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