Health-care electronics

The market, the challenges, the progress

Wolfgang Eberle[1], Ashwin S. Mecheri[1,2],
Thi Kim Thoa Nguyen[1,2], Georges Gielen[2]
[1] IMEC, Bioelectronic Systems Group, Leuven, Belgium,
[2] KU Leuven, MICAS, Leuven, Belgium
wolfgang.eberle@imec.be

Raymond Campagnolo[3], Alison Burdett[4],
Chris Toumazou[5], Bart Volckaerts[6]
[3] CEA LETI, MINATEC, Grenoble, France,
[4] Toumaz Technology Ltd., Oxford, UK,
[5] Institute of Biomed. Eng., Imperial College London, UK,
[6] Cochlear Technology Centre, Mechelen, Belgium

***Abstract*— Exploding health care demands and costs of aging and stressed populations necessitate the use of more in-home monitoring and personalized health care. Electronics hold great promise to improve the quality and reduce the cost of health care. The speakers in this hot topic session will discuss the field of health care electronics from all aspects. First, the market of health care electronics is described, and realities, trends and hypes will be pointed out. The second presentation describes the engineering challenges in ultra low-power disposable electronics for wireless body sensor applications. Both the sensor aspects, the related signal processing, and business models will be discussed. The third presentation talks about embedded bio-stimulation applications in cochlea implants, thereby highlighting the design challenges in terms of power consumption and extreme reliability of these devices. The final presentation discusses the application of brain stimulation and recording with respect to artifact reduction and field steering, and describes aspects of the modeling and design strategy. In this way, this hot-topic session offers the attendees a complete picture of the field of health-care electronics, ranging from the business to the technological and design aspects.**

Keywords-health-care, medical electronics, implants, embedded SoC, wireless body sensor networks, neural stimulation, eletrical field modeling, FEM.

I. REALITIES AND TRENDS IN MEDICAL ELECTRONICS

The Medical Electronics field is constantly advancing on many fronts from diagnostic imaging devices and large scale equipments to portable and implanted devices. First, we will give an overview of the Medical Electronics market and its main growth drivers (demographic drivers, health care providers and biotechnology, nanotechnology and infotech convergence). Examples of themes for present and future (diagnostic, cardiology, neurology, monitoring, retinal prosthesis, wireless, etc.) will be highlighted. Future trends will be discussed within three medical sectors (diagnostic, portable and implantable devices) and we will try to identify remaining gaps and challenges. As healthcare technology migrates towards personalized medicine and into the home, we will conclude that "Consumer Medical Electronics Market" would be one of the main opportunities for the semiconductor industry.

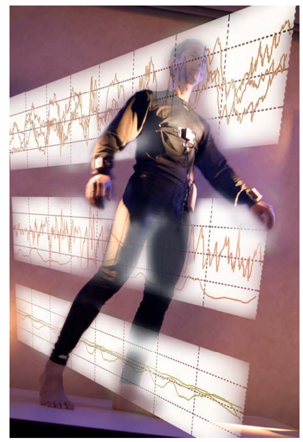

Figure 1. Wearable motion capture system for medical applications.

II. WIRELESS BODY SENSOR NETWORKS: SYSTEM-ON-CHIP DEVELOPMENT

Wireless body sensor networks (WBSN) consist of sensor nodes used to monitor vital signs such as temperature, heart rate and electrocardiogram (ECG/EKG). These sensor nodes gather, store and locally process vital signs data, before transmission to a central base-station node. Although prototype modules for such WBSN applications are becoming available, these devices tend to be multi-chip solutions manufactured from off the shelf components, and suffer excessive power consumption and relatively large form factors. Improvements to the patient's quality of care can be achieved through miniaturization and power consumption reduction, which dictates the development of a custom system-on-chip (SoC). Although ultra low power wireless transceiver ASICs have previously been reported, in this paper we describe the integration of a system solution with a full custom hardware MAC, digital microprocessor core and I/O peripherals, on-chip memory, micropower ADC, wireless transceiver and custom sensor interfaces. This SoC platform device is capable of achieving ubiquitous medical monitoring when interfaced to appropriate body worn sensors, and represents state-of-the art in terms of functionality and ultra low power consumption.

The encapsulated wireless sensor node is in the form of a thin and flexible patch, comprising sensors, SoC, battery and antenna. The patch is attached to the patient for a period of

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typically 4-7 days, after which it is thrown away and a new patch attached if necessary. The battery is manufactured from environmentally-friendly materials such that it can be recycled or safely disposed of, and provides typically $3mAh/cm^2$ at 1.4V, dropping to 0.9V at end of battery life. The limited energy capacity means that the average current drain must be of the order of uA to achieve the target operating lifetime. In addition the battery peak currents must be limited to be no higher than a few mA to avoid battery collapse.

These energy constraints require a novel low power design methodology to be applied at all levels – network protocol, system architecture, circuit topology and implementation – in order to guarantee reliable and robust operation within the battery's maximum peak current discharge capacity. The SoC comprises three major sections; sensor interface, digital baseband and wireless transceiver.

The sensor interface is designed to support a number of different types for monitoring applications including: glucose/pH using amperometric sensors; motion using a 3-axis accelerometer; heart rate/ECG (EKG) using a single lead electrode; temperature using thermistors; pressure using a Wheatstone bridge. A block diagram of the sensor interface circuitry is shown in Figure 2. Mixed signal circuitry provides gain, filtering, biasing and buffering of the sensor inputs. The embedded digital processor may be used for sensor calibration to ensure excellent offset and gain accuracy. A 10bit ΔΣ analogue to digital converter samples sensor input signals within a dc to 250 Hz bandwidth. The ADC is a third order switched operational amplifier (SO) implementation with a 64 times oversampling ratio. Due to the low frequency nature of the input physiological signals, minimization of dc offsets and 1/f noise is crucial. Optimal switch sizing was key to minimizing 1/f noise while achieving low current consumption.

The transceiver is described in more detail in [1]. Its receiver uses a two stage zero IF architecture based on a sliding IF approach which provides advantages in filtering and noise profiling and thus allows a lower current consumption than a single stage direct conversion architecture. The PA stage is designed to deliver -10dBm into a matched antenna load, giving a range of typically 10m indoors.

The digital section contains the 8051 advanced architecture processor, peripherals, memories, timers and MAC. The MAC protocol block is a custom design to ensure ultra-low power operation while guaranteeing robust performance, and controls the RF channel selection, LBT compliance, link establishment, data transfer and sleep management.

The network adopts a master-slave architecture. Unlike traditional peer-to-peer wireless sensor networks, the nodes in this biomedical WBSN are not deployed in an ad hoc fashion. Joining a network is centrally managed and all communications are single-hop. To reduce energy consumption, all the sensor nodes are in standby or sleep mode until the centrally assigned time slot. Once a node has joined a network, there is no possibility of collision within a cluster as all communication is initiated by the central node and is addressed uniquely to a slave node. To avoid collisions with nearby transmitters, a clear channel assessment algorithm based on standard listen-before-transmit (LBT) is used. To handle time slot overlaps, the novel concept of a wakeup fallback time is introduced. Using single-hop communication and centrally controlled sleep/wakeup times leads to significant energy reductions for this application compared to more 'flexible' network MAC protocols such as Zigbee.

A direct memory access (DMA) controller ensures that data samples from the ADC can be continually written to the data memory while at the same time allowing previous data samples to be passed to the microprocessor for processing, or to the MAC for encoding prior to transmission. Up to three independent sensors can be connected to a single SoC, and the sample interval and number of samples per sample time can be independently set for each sensor – this allows sensors with different speed and accuracy requirements (e.g. temperature vs. ECG) to be optimally sampled. These control functions are implemented in hardware, thus in operation the microprocessor core is essentially 'free' to run any user-defined application code; for example, fusing data from multiple sensors to allow intelligent decision making.

The Sensium™ SoC is implemented in a 0.13µm CMOS technology. The chip microphotograph is shown in Figure 5 and occupies an area of $16mm^2$. Full functionality for centre-processed samples has been verified down to 0.85V; initial yield across corner lots is greater than 95% at a test time of < 3s on a Teradyne J750.

This device is the first SoC designed specifically for wireless vital signs monitoring and represents state of the art in terms of functionality and ultra low power operation. In WBSN applications this SoC is able to provide typically one to two orders of magnitude lower power consumption than competing solutions, and thus offers the possibility for truly unobtrusive and disposable vital sign monitoring.

We are entering new waves of technology inspired by life style, healthcare, and quality of life. Demands on healthcare throughout the world are changing. The global demographic trend towards ageing populations, coupled with less active lifestyles and fast-food diets, is leading to higher probability and earlier onset of chronic conditions such as Type 2 diabetes and cardiovascular disease. This, in turn, is translating to a substantial increase in the proportion of resources required for long-term, continuous care and a growing burden on healthcare infrastructures.

This talk will review some of the author's work at attempts to provide sensor processing solutions. It will also include his work on a wireless body wave disposable 'digital' plaster, a novel 'low powerless' blood pressure monitor and a point-of-care genetic disposable chip, all created from technologies stemming from the semi-conductor industry. Business models and more technologies will be discussed.

III. IMPLANTABLE HEARING PROSTHESIS: HOW INTERDISCIPLINARY RESEARCH AND DEVELOPMENT REVOLUTIONIZE HEARING

A. *Introduction*

People with severe to profound bilateral hearing loss cannot sufficiently regain sound perception by using conventional hearing aids. In numerous cases, the only suitable solution consists of bypassing the damaged part of the ear and sending sound signals directly to the auditory (hearing) nerve via electrical stimulation to provide a clearer understanding of sound and speech. This operation can be performed today with a Cochlear Implant. As a major provider of implantable hearing solutions, Cochlear has given over 100 000 people the opportunity to reconnect to a world of sound.

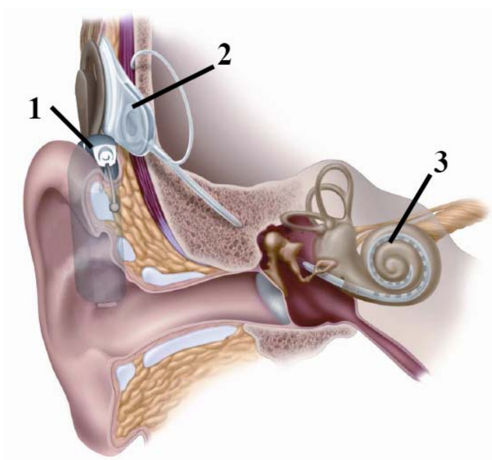

Figure 2. Present cochlear implants consist of a sound processor (1) worn behind the ear, a receiver–stimulator (2) and an electrode array (3) implanted in the cochlea.

All current Cochlear Implants consist of a sound processor worn behind the ear containing a microphone set that converts sound into electrical voltages (Fig. 2). The code produced by the speech processor, together with power, is transmitted by magnetic waves via a circular aerial through the recipient's intact skin to the receiver–stimulator implanted in the mastoid bone. The receiver–stimulator decodes the signal and produces a pattern of electrical stimulation currents in a bundle of electrodes inserted around the internal central part of the inner ear, called modiolus, to stimulate the auditory nerve fibers. A pattern of hearing nerve activity in response to sound is produced, and provides a meaningful representation of speech and environmental sounds.

B. *Latest trends in electrode design and manufacturing*

Different types of commercial and research electrode arrays are highlighted to demonstrate the present challenges in design and development of active implantable medical systems.

The Contour Advance^{TM} (CA) electrode is Cochlear's latest electrode product. During manufacturing, the CA electrode is molded curled and then held straight with a stylet. The electrode plus stylet are first inserted into the cochlea. Then, as the electrode is advanced off the stationary stylet, it curls around the modiolus due to the memory of the silicone. The CA electrode settles in a perimodiolar position with the silicone in its coiled resting state and the platinum stimulation contacts facing towards the auditory nerve fibers in the modiolus. We will show in the presentation that the CA electrode array with Advance Off-Stylet^{TM} insertion technique provides the opportunity for the least traumatic cochlear insertion which is critical to optimize recipients outcomes in terms of speech understanding.

One of the challenges with present electrode arrays for Cochlear Implants relate to the development of a technology capable of increasing the number of stimulation sites. In combination with the appropriate speech processing strategies, such a system could potentially lead to significant improvements in music appreciation and speech perception in noisy conditions. We present here a process to build perimodiolar electrode arrays where the Pt stimulation sites are combined with silicon chips, bringing active circuitry to the inner cochlea. The interconnect technology is based on an intra-cochlear bus structure, thereby replacing the need to connect each stimulation site to the receiver–stimulator by a separate direct wire connection.

Another electrode array showing potential for the next generation of Cochlear Implants is the intra-modiolus electrode array. These electrodes will not be implanted in the scala tympany of the cochlea as is common in cochlear implantation today, but straight into the nerve bundle located in the modiolus. The expected advantage of this approach is that there is less risk of damage to delicate structures in the cochlea, including the basilar membrane and the (remaining) hair cells, and therefore better preservation of any residual hearing that may be present. Since the modiolus electrode is in direct contact with the nerve, the expectation is that less electrical power will be consumed to produce equivalent loudness sensation compared to the standard scala tympany electrodes.

IV. BRAIN IMPLANTS FOR TREATMENT OF NEUROLOGIC DISORDERS: DESIGN AND MODELING STRATEGY

Medical therapies around brain diseases rely on electrical stimulation with implanted probes as a last resort. Applying semiconductor process technology together with advanced electronic signal processing allows to move brain probes for electrical stimulation and recording an important step further: increasing spatial and temporal resolution of signals allows the improvement of existing therapies for deep brain diseases such as Parkinson's disease or tremor but also the development of new therapeutic targets such as for obsessive-compulsive disorder (OCD). A design strategy starting from bio-electrical finite-element modeling of the electrical field distribution towards mixed-signal artifact reduction for simultaneous stimulation and recording are outlined.

A. *FEM-based electrode optimization for desired electrical field distribution in tissue*

Electrical deep brain stimulation is a valuable last resort for the treatment of severe brain disorders when pharmaceutical drugs have proven to be ineffective for a particular patient. Despite clinical use for several decades, details of how DBS works are still not understood. Present day stimulation is performed using e.g. Medtronic's probes, which have millimeter-size contacts leading to a highly unfocused stimulation of a large area which induces significant unwanted side effects in neighboring areas. To have a more appropriate resolution in terms of recording and stimulation we need electrodes of the same dimension as that of a neuron. Neural probes with electrodes in the dimensions of 25 to 50 µm [2] help us achieve the required resolution for recording and stimulation.

An efficient way to get early insight into the differences in electrical field distribution and understanding how we can use this variety for DBS applications is to use finite element modeling (FEM). However, in the case of planar electrode these studies have only investigated the field distribution from a single electrode.

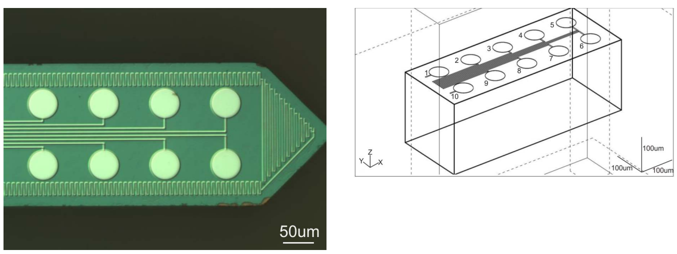

Figure 3. Photograph of part of the actual probe (left) and geometrical build-up of a 50µm probe in COMSOL (right).

In the case of multiple small electrodes, investigating the effect of neighboring electrodes and various electrode functionalities is required on the full probe model. We investigate here the full microfabricated 10-electrode model (Fig. 3).

A 3-dimensional model of the probe and the surrounding tissue was modeled and simulated in COMSOL 3.4. The probe has dimensions of 525 x 200 x 200 µm^3. The whole probe is surrounded by homogenous tissue (σ = 0.3 S/m) of 2 x 2 x 2 mm^3 volume with the electrode assembly in the center. The large volume of tissue is chosen so as to have a realistic near field potential distribution around the electrode. The probe model is based on the actual fabrication details.

The model was built up in a parametrizable and modular way in COMSOL script starting from basic layered elements towards subcomponents such as the wires or the electrodes. This approach arranges all probe features in separate parameterized vertical stacks to allow a perfect alignment of all subdomains. It also facilitates meshing of the various subdomains of the model in a stepwise way with the smallest element being meshed first and then moving on to larger elements within the model. The model modularity allows automation of the process. Mapped-mesh parameters were used to mesh the model in a partially automated mode guided by minimum mesh quality information provided by the user. A total of 821377 tetrahedral elements are present which have 1096854 degrees of freedom. The probe and the electrode are made of 612976 and 2823 tetrahedral respectively.

AC/DC quasi-static electromagnetic physics was used to solve the simulation with the transient time solver under standard settings for a time period of 1 ms with a single tone as stimulation waveform. A single simulation run takes about 10 hours on single core of a HP DL165G5 2 x quad-core server with 16-GByte memory.

The classical form of deep brain stimulation is to use a stimulating electrode in the deep brain and to use a large counter electrode on the skull. However, a multi-contact probe allows local counter electrodes.

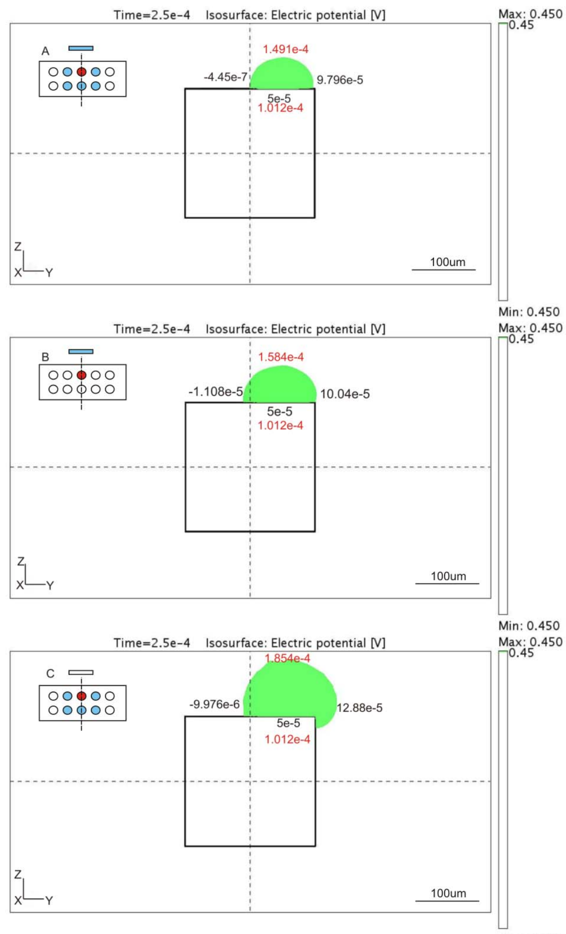

Figure 4. (A) Neighboring and distant electrodes grounded. (B) Distant electrode grounded: 19% better field penetration than (A). (C) Neighboring electrodes grounded: 75% better field penetration than (A).

Studies were done (Fig. 4) to see if we could make use of having multiple electrodes on a single probe to achieve a better stimulation pattern. We considered 3 different conditions for this: (A) the neighboring electrode and the distant electrode grounded, (B) the classical case of distant large counter electrode, and (C) only the neighboring electrode was grounded. All the cases have only one stimulation electrode

(electrode 3) for which the results are shown. All other non-grounded electrodes are left floating. The results indicate clearly that the penetration depth corresponding to a particular desired iso-surface potential and asymmetry can be controlled by configuring neighboring electrodes appropriately. Adapting penetration depth and field asymmetry in this way allow for a certain level of field steering which introduces a higher spatial selectivity of the stimulation as desired for DBS applications. We can thus reduce the stimulation current without loosing penetration depth or increase penetration depth for the same current.

The addition of the electrical double layer and a tissue heterogeneity model are important next steps to validate these findings in a more realistic model and allow comparison with in vitro and in vivo measurements. Further investigation will go into multiple electrode stimulation and also using the other electrodes with lower voltage levels or for bipolar stimulation to better control the field steering capabilities of the electrode topology.

B. *Mixed-signal stimulus artifact reduction for simultaneous stimulation and recording*

Basically all implants today use either stimulation or recording only or they use a time-interleaved scheme such that the typically stimulation signals (e.g. 1-5V) do not interfere with the very low recording signal levels (e.g. 10-50 µV). A variety of compensation schemes has been devised but most of them are used to reduce the unavailable time of the analog electronics due to saturation; in electrophysiology, this often means that several milliseconds after a stimulation pulse are lost. When moving to multi-electrode arrays with multiple stimulation electrodes, valuable recording information is lost.

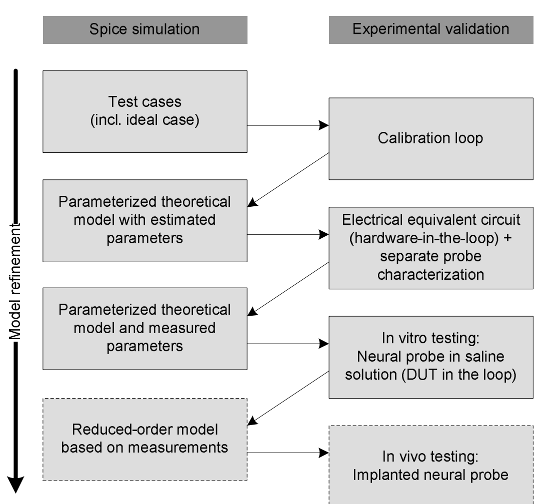

Figure 5. Incremental refinement flow for development & testing approach.

We have devised a mixed-signal compensation scheme [3] which deals with such artifacts in a different way. From a design perspective, appropriate modeling and testing of the algorithms against the models and experimental validation is crucial. The following quasi-parallel approach has been used with step-wise improvement of the device-under-test (DUT) and refinement of the simulation model.

The basic idea of template subtraction is applied in a digitally-controlled analog hybrid context. Analog subtraction preserves dynamic range and linearity while the digital control allows accurately and fast controlling the remaining artifacts in well-known time region. Our prototype system (Fig. 1) uses a MATLAB-controlled NI DAQ card with external discrete electronics and two 12-bit D/A output (stimulation and compensation signal) and one 12-bit A/D input channel (recording). A common sampling rate of 100 kHz was used.

The system operates in three steps which can be periodically repeated on demand: (1) calibration of the electronics path, (2) artifact estimation (training phase), (3) artifact compensation during stimulation and recording. Along with the system operation, modeling and experimental testing aspects will be illustrated. Quantitative measurements show that template subtraction reduces the average artifact voltage by a factor of 40.8 with an additional gain of about 2.5 due to blanking and digital interpolation.

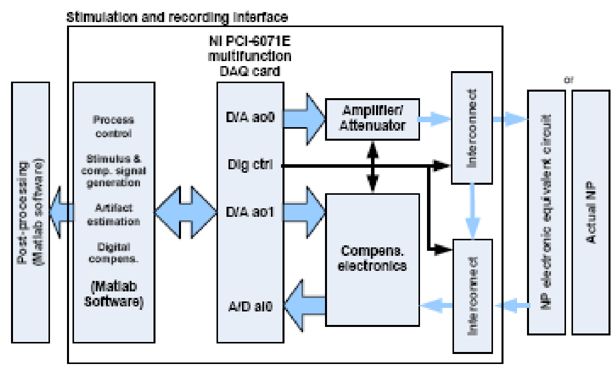

Figure 6. A hybrid DBSR system with artifact reduction.

First results of the i*n vitro* testing of the system with actual 50-µm contact-size neural probes in physiological saline solution with. higher gains up to 500 for the recording amplifier have been succesfully tested. The algorithm has been refined to perform tracking and compensation of the statistical random electrochemical DC offset voltage originating from the electrochemical interface potential. Improved reduced-order models that also cover the large-signal characteristics of the electrochemical interface are currently developed.

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